PROGENICS PHARMACEUTICALS INC

FORM 10-Q
(Quarterly Report)

Filed 5/10/2005 For Period Ending 3/31/2005

Address	777 OLD SAW MILL RIVER ROAD
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Telephone	914-789-2800
CIK	0000835887
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2005

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number **000-23143**

PROGENICS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**13-3379479**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

777 Old Saw Mill River Road
Tarrytown, New York 10591
(Address of principal executive offices)
(Zip Code)

(914) 789-2800
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No ☐

As of May 6, 2005 there were 19,572,360 shares of common stock, par value $.0013 per share, of the registrant outstanding.

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Part I – FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

PROGENICS PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS

(in thousands, except for par value and share amounts)
(Unaudited)

	March 31, 2005	December 31, 2004
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 5,820	$ 5,227
Marketable securities	16,831	24,994
Accounts receivable	728	1,112
Amount due from joint venture	744	189
Other current assets	1,170	1,810
Total current assets	25,293	33,332
Marketable securities	981	986
Fixed assets, at cost, net of accumulated depreciation and amortization	4,474	4,692
Restricted cash	534	535
Total assets	$ 31,282	$ 39,545
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable and accrued liabilities	$ 9,055	$ 7,260
Investment deficiency in joint venture	403	405
Total current liabilities	9,458	7,665
Deferred lease liability	40	42
Total liabilities	9,498	7,707
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.001 par value, 20,000,000 shares authorized; none issued and outstanding		
Common stock–$.0013 par value, 40,000,000 shares authorized; issued and outstanding 17,516,298 in 2005 and 17,280,635 in 2004	23	22
Additional paid-in capital	156,372	153,469
Unearned compensation	(2,015)	(2,251)
Accumulated deficit	(132, 505)	(119,311)
Accumulated other comprehensive income (loss)	(91)	(91)
Total stockholders' equity	21,784	31,838

Total liabilities and stockholders' equity	$ 31,282	$ 39,545

The accompanying notes are an integral part of these condensed financial statements.

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PROGENICS PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS

(in thousands, except net loss per share)
(Unaudited)

	Three months ended March 31,	
	2005	**2004**
Revenues:		
Contract research and development from joint venture	$ 440	$ 557
Research grants and contracts	2, 145	1,186
Product sales	4	5
Total revenues	2,589	1,748
Expenses:		
Research and development	12,099	8,374
General and administrative	3,143	2,815
Loss in joint venture	205	675
Depreciation and amortization	482	326
Total expenses	15,929	12,190
Operating loss	(13,340)	(10,442)
Other income:		
Interest income	146	217
Net loss	$ (13,194)	$ (10,225)
Net loss per share – basic and diluted	$ (0.76)	$ (0.61)
Weighted-average shares – basic and diluted	17,420	16,708

The accompanying notes are an integral part of these condensed financial statements.

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PROGENICS PHARMACEUTICALS, INC.
CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS
FOR THE THREE MONTHS ENDED MARCH 31, 2005

(in thousands)
(Unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN	UNEARNED	ACCUMULATED	ACCUMULATED OTHER COMPREHENSIVE	TOTAL STOCKHOLDERS'	COMPREHENSIVE
	Shares	Amount	CAPITAL	COMPENSATION	DEFICIT	LOSS	EQUITY	LOSS
Balance at December 31, 2004	17,281	$22	$153,469	($2,251)	($119,311)	($91)	$31,838	($42,124)
Issuance of Restricted Stock, net of forfeitures	(1)		(43)	43				
Amortization of unearned compensation				193			193	
Issuance of compensatory stock options			140				140	
Sale of Common Stock under employee stock purchase plans and exercise of stock options	236	1	2,806				2,807	
Net (loss)					(13,194)		(13,194)	(13,194)
Change in unrealized gain on marketable securities							0	0
Balance at March 31, 2005	17,516	$23	$156,372	($2,015)	($132,505)	($91)	$21,784	($13,194)

The accompanying notes are an integral part of these condensed financial statements.

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PROGENICS PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS

(in thousands)
(Unaudited)

	Three month ended March 31,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (13,194)	$ (10,225)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	482	326
Amortization of discounts, net of premiums, on marketable securities	77	202
Amortization of unearned compensation	193	
Noncash expenses incurred in connection with issuance of common stock and stock options	140	156
Loss in joint venture	205	675
Adjustment to loss in joint venture	293	134
Changes in assets and liabilities:		
Decrease in accounts receivable	384	515
Increase in amount due from joint venture	(555)	(582)
Decrease in other current assets and other assets	640	356
Increase (decrease) in accounts payable and accrued expenses	1,795	(83)
Increase in investment in Joint Venture	(500)	(950)
Decrease in deferred lease liability	(2)	(2)
Net cash used in operating activities	(10,042)	(9,478)
Cash flows from investing activities:		
Capital expenditures	(264)	(542)
Decrease (increase) in restricted cash	1	(1)
Sales of marketable securities	13,541	23,990
Purchase of marketable securities	(5,450)	(19,448)
Net cash provided by investing activities	7,828	3,999
Cash flows from financing activities:		
Proceeds from the exercise of stock options and sale of common stock under the Employee Stock Purchase Plan	2,807	1,924
Net cash provided by financing activities	2,807	1,924
Net increase (decrease) in cash and cash equivalents	593	(3,555)
Cash and cash equivalents at beginning of period	5,227	11,837
Cash and cash equivalents at end of period	$ 5,820	$ 8,282
Supplemental disclosure of noncash investing and financing activities:		
Net fixed assets included in accounts payable and accrued expenses:		$ 10

The accompanying notes are an integral part of these condensed financial statements.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share amounts or unless otherwise noted)

1. Interim Financial Statements

Progenics Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. The Company's principal programs are directed toward symptom management and supportive care and the treatment of Human Immunodeficiency Virus ("HIV") infection and cancer. The Company was incorporated in Delaware on December 1, 1986. All of the Company's operations are located in New York. The Company operates in a single segment.

With the exception of the years ended December 31, 1997 and 1998, the Company has had recurring losses and had, at March 31, 2005, an accumulated deficit of approximately $132.5 million. At March 31, 2005, the Company had cash, cash equivalents and marketable securities, including non-current portion, totaling $23.6 million. During the quarter then ended, the Company had a net loss of $13.2 million and used cash in operating activities of $10.0 million. Other than potential revenues from methylnaltrexone ("MNTX"), which could occur as early as late 2006, the Company does not anticipate generating significant recurring revenues, from product sales or otherwise, in the near term, and the Company expects its expenses to increase. Consequently, the Company will require significant additional external funding to continue its operations at the current levels.

On April 6, 2005, the Company received $29.4 million, net of underwriting discounts and offering expenses, through a public offering of 2.0 million shares of its common stock. The Company expects that the proceeds from this offering, together with cash, cash equivalents and marketable securities at March 31, 2005, will be sufficient to fund current operations through mid-2006. The Company would, however, expect to raise additional funds, or implement significant cost-saving measures, by the end of 2005. The Company is seeking to obtain additional funding from potential collaboration agreements with one or more pharmaceutical companies. The Company is currently in negotiations with potential collaborators for MNTX programs, and the Company is seeking to finalize a collaboration agreement in 2005. The Company expects that such a collaboration agreement would include up-front license fees or other payments as well as milestone payments. The Company also expects that a collaborator would assume some or all of the financial responsibility for further clinical development and commercialization of a majority of the MNTX programs. The Company may also enter into a collaboration agreement, or license or sale transaction, with respect to other of its product candidates. The Company may also seek to raise additional capital through the sale of its common stock or other securities and expects to fund aspects of its operations through government grants and contracts.

Adequate additional funding may not be available to the Company on acceptable terms or at all. The Company has the ability to make cost-saving changes in its operations in the event that the Company is unable to secure additional funding. Such changes would likely involve focusing the Company's resources on its late-stage MNTX program, which the Company believes has the greatest likelihood of generating near-term cash flows, and reducing or eliminating funding to some or all of its other programs. The Company believes that these measures would significantly reduce its operating expenses. The extent to which these changes will be implemented, if at all, will depend upon a variety of factors, including cash in-flows from collaborations, financings or other sources, the extent to which negative cash flows from operations continue and the perceived likelihood of success, and expected costs to completion, of the Company's various product development programs.

The interim Condensed Financial Statements of the Company included in this report have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations and cash flows in conformity with generally accepted accounting principles. In the opinion of management, these financial statements reflect all adjustments, consisting primarily of normal recurring accruals, necessary for a fair statement of results for the periods presented. The results of operations for interim periods are not necessarily indicative of the results for the full year. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2004.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (continued)
(amounts in thousands, except share and per share amounts or unless otherwise noted)

2 . Change in Accounting Policy- Revenue Recognition

During the quarters ended March 31, 2005 and 2004, the Company recognized revenue from PSMA Development Company LLC (the "JV") (a related party), the Company's joint venture with Cytogen Corporation, for contract research and development (see Note 7); from government research grants and contracts from the National Institutes of Health (the "NIH"), which are used to subsidize certain of the Company's research projects ("Projects"), and from the sale of research reagents.

Effective January 1, 2005, the Company elected to change the method it uses to recognize revenue under SAB 104 for payments received under research and development collaboration agreements that contain substantive at-risk milestone payments. There was no cumulative effect of this change in accounting principle because the Company does not currently have any of these contracts. Under the new method, non-refundable up-front license payments received from collaborators, not tied to achieving a specific performance milestone, are recognized as revenue ratably over the period during which the Company expects to perform services, because no separate earnings process has been completed. Payments for research and development activities are recognized as revenue as the related services are earned by the Company. Substantive at-risk milestone payments, which are based on the Company achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, provided there is no future service obligation on the part of the Company associated with that milestone (the "Substantive Milestone Method"). The change in accounting method was made because the Company believes that it will enhance the comparability of its financial results with those of its peer group companies in the biotechnology industry and because it is expected to better reflect the substance of the Company's collaborative arrangements.

Previously, the Company had recognized non-refundable fees, including payments for services, up-front licensing fees and milestone payments, as revenue based on the percentage of efforts incurred to date, estimated total efforts to complete, and total expected contract revenue in accordance with EITF Issue No. 91-6, "Revenue Recognition of Long-Term Power Sales Contracts," with revenue recognized limited to the amount of non-refundable fees received. Depending on the magnitude and timing of milestone payments, revenue may be recognized sooner under the Substantive Milestone Method than it would have been under the EITF 91-6 model.

The accounting change will not affect revenue from NIH grants and contracts, services performed on behalf of the JV, or from product sales.

NIH grant and contract revenue is recognized as efforts are expended and as related subsidized Project costs are incurred. The Company performs work under the NIH grants and contract on a best-efforts basis. The NIH reimburses the Company for costs associated with the preclinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus, as requested by the NIH. Substantive at-risk milestone payments are uncommon in these arrangements, but would be recognized as revenue on the same basis as the Substantive Milestone Method.

Both the Company and Cytogen are required to fund the JV equally to support ongoing research and development efforts conducted by the Company on behalf of the JV. The Company recognizes payments for research and development as revenue as services are performed. For the quarters ended March 31, 2005 and 2004, the Company recognized approximately $0.4 million and $0.6 million, respectively, of contract research and development revenue for services performed on behalf of the JV.

For three months ended March 31, 2005 and 2004, the Company's research grant and contract revenue and contract research and development revenue came exclusively from the NIH and the JV, respectively.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (continued)
(amounts in thousands, except share and per share amounts or unless otherwise noted)

3. Stock-Based Employee Compensation

The accompanying statements of financial position and results of operations have been prepared in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"). Under APB No. 25, generally no compensation expense is recognized in the financial statements in connection with the awarding of stock option grants to employees provided that, as of the grant date, all terms associated with the award are fixed and the fair value of the Company's stock, as of the grant date, is equal to or less than the amount an employee must pay to acquire the stock. The Company recognizes compensation expense if the terms of an option grant are not fixed or the quoted market price of the Company's common stock on the grant date is greater than the amount an employee must pay to acquire the stock. Compensation expense is also recognized for performance-based vesting of stock options upon achievement of defined milestones. Unearned compensation for restricted stock awards granted is recorded on the date of the grant based on the intrinsic value of such awards. Such unearned compensation is expensed using a straightline method as the related restrictions on such stock lapse.

The Company intends to adopt Statement of Financial Accounting Standards No. 123 (revised 2004) "Share-Based Payment" ("SFAS No.123R") on January 1, 2006, using the modified prospective application (see Note 10). In anticipation of the adoption of SFAS No.123R, the Company has revised certain assumptions used in the Black-Scholes option pricing model to value equity-based awards. The estimate of expected term has been increased from 5 years to 6.5 years for all awards granted on or after January 1, 2005, in accordance with the simplified method described in Staff Accounting Bulletin No. 107 for options with five-year graded vesting. The period used to calculate historical volatility of the Company's common stock has also been revised to 6.5 years. The impact of these revisions is expected to increase the amount of compensation expense recognized by the Company as compared to the amount that would have been recognized using the previous estimates.

The following table summarizes the pro forma operating results and compensation costs for the Company's incentive stock option and stock purchase plans, which have been determined in accordance with the fair value-based method of accounting for stock-based compensation as prescribed by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"). Since option grants and restricted stock awarded during 2005 and 2004 vest over several years and additional awards are expected to be issued in the future, the pro forma results shown below are not likely to be representative of the effects on future years of the application of the fair value-based method.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (continued)
(amounts in thousands, except share and per share amounts or unless otherwise noted)

	Three Months Ended March 31,	
	2005	2004
Net loss, as reported	$ (13,194)	$ (10,225)
Add: Stock-based employee compensation expense included in reported net loss	205	
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(1,813)	(2,431)
Pro forma net loss	$ (14,802)	$ (12,656)
Net loss per share amounts, basic and diluted:		
As reported	$ (0.76)	$ (0.61)
Pro forma	$ (0.85)	$ (0.76)

For the purpose of the above pro forma calculations, the fair value of each option granted was estimated on the date of grant using the Black-Scholes option pricing model. The following assumptions were used in computing the fair value of options granted: expected volatility of 92% in 2005 and 2004 (47% for the employee stock purchase plan), expected lives of 6.5 years in 2005 and 5 years in 2004 (six months for the employee stock purchase plan), zero dividend yield, and weighted-average risk-free interest rates of 3.29% in 2005 and 3.10% in 2004.

The fair value of options and warrants granted to non-employees for services, determined using the Black-Scholes option pricing model with the foregoing assumptions, is included in the financial statements and expensed as they vest. Net loss and pro forma net loss include $128 and $156 of non-employee compensation expense in the three month periods ended March 31, 2005 and 2004, respectively.

In March 2005, upon achievement of a defined performance milestone, an officer vested 5,520 stock options for which the Company recognized approximately $12 of non-cash compensation expense in accordance with APB No. 25.

4. Revised Classification of Certain Securities

At December 31, 2004, the Company had reclassified its auction rate securities as marketable securities in current assets. Prior to that reclassification, such investments had been classified as cash and cash equivalents. Accordingly, the Company has reflected these securities as marketable securities in the current assets section of its balance sheets as of March 31, 2005, December 31, 2004 and 2003. The Company has also made corresponding adjustments to its statements of cash flows for the quarters ended March 31, 2005 and 2004 to reflect the gross purchases and sales of these securities as investing activities rather than as a component of cash and cash equivalents since the effect of such reclassifications would have been reflected in the Company's March 31, 2004 balance sheet. This reclassification does not affect previously reported cash flows from operations or from financing activities in the Company's previously reported statements of cash flows or its previously reported statements of operations for any period.

At December 31, 2003 and March 31, 2004, $35.9 and 25.6 million, respectively, of these current investments had originally been classified as cash equivalents on the Company's balance sheet. These investments have been reclassified to short-term investments from cash and cash equivalents as previously reported.

For the quarter ended March 31, 2004, $10.3 million of net cash provided by investing activities resulted from the reclassification of these short-term auction rate securities.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (continued)
(amounts in thousands, except share and per share amounts or unless otherwise noted)

5 . Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2005 and December 31, 2004 consist of the following:

	March 31, 2005	December 31, 2004
Accounts payable	$ 622	$ 1,438
Accrued consulting and clinical trial costs	6,541	3,832
Accrued payroll and related costs	428	734
Legal and professional fees payable	1,168	1,256
Other	296	
	$ 9,055	$ 7,260

6 . Net Loss Per Share

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of common shares outstanding during the respective periods. For the three months ended March 31, 2005 and 2004, the Company reported a net loss and, therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of net loss per share, basic and diluted, are as follows:

	Net Loss (Numerator)	Shares (Denominator)	Per Share Amount
Three months ended March 31, 2005			
Basic and Diluted	$ (13,194)	17,420	$ (0.76)
Three months ended March 31, 2004			
Basic and Diluted	$ (10,225)	16,708	$ (0.61)

Common stock equivalents, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, consist of the following:

	Three Months Ended March 31,			
	2005		2004	
	Wtd. Avg. Number	Wtd. Avg. Exercise Price	Wtd. Avg. Number	Wtd. Avg. Exercise Price
Stock options	4,806	$ 10.08	5,150	$ 10.19
Restricted stock	176			
Total	4,982		5,150	

7. PSMA Development Company LLC

PSMA Development Company LLC (the "JV") was formed on June 15, 1999 as a joint venture between the Company and Cytogen Corporation (each a "Member" and collectively, the "Members") for the purposes of conducting research, development, manufacturing and marketing of products related to prostate-specific membrane antigen ("PSMA"). Each Member has equal ownership and equal representation on the JV's management committee and equal voting rights and rights to profits and losses of the JV. In connection with the formation of the JV, the Members entered into a series of agreements, including an LLC Agreement and a Licensing Agreement (collectively, the "Agreements"), which generally define the rights and obligations of each Member, including the obligations of the Members with respect to capital contributions and funding of research and development of the JV for each coming year. The Agreements generally terminate upon the last to expire of the patents granted by the Members to the JV or upon breach by either party, which is not cured within 60 days of written notice or upon dissolution of the JV in accordance with the LLC Agreement.

The Company provides research and development services to the JV and is compensated for its services based on agreed upon terms. Until January 2004, such services were provided to the JV pursuant to a Services Agreement and extensions thereof. The Services Agreement, as extended, expired effective January 31, 2004, and the Members have not yet agreed upon the terms of a replacement services agreement. The Services Agreement provided that all inventions made by the Company in connection with its research and development services for the JV are to be assigned to the JV for its use and benefit.

The Company was required to fund the initial cost of research up to $3.0 million. As of December 31, 2001, the Company had surpassed the $3.0 million in funding for research costs. Each Member thereafter made equal capital contributions to fund research costs. Such contributions, in total, were $1.0 million, and $1.9 million in the three month periods ended March 31, 2005 and 2004, respectively. Each Member made a capital contribution to the JV of $0.5 million in January 2005, which was used to fund obligations outstanding regarding work performed under the approved 2004 work plan.

The level of commitment by the Members to fund the JV is based on an annual budget and work plan that is developed by the Members. The budget is intended to provide for sufficient funds to conduct the research and development projects specified in the work plan for the then-current year. At March 31, 2005, the JV had no approved budget or work plan for the year ending December 31, 2005 because the Company and Cytogen had not yet reached agreement with respect to a number of matters relating to the JV. However, the Members have approved the JV's expenses for the quarter ended March 31, 2005 and have both the intent and ability to fund those expenses. The Members are in discussions to finalize a work plan and budget for the remainder of the year ending December 31, 2005. However, they may not succeed in doing so.

Amounts received by the Company from the JV as payment for research and development services and reimbursement of related costs in excess of the initial $3.0 million provided by the Company (see above) are recognized as contract research and development revenue. For the three months ended March 31, 2005 and 2004, such amounts totaled approximately $440 and $557, respectively. According to the Agreements, the Company may directly pursue and obtain government grants directed to the conduct of research utilizing PSMA related technologies. In consideration of the Company's initial incremental capital contribution of $3.0 million of joint venture research expenditures, the Company may retain $3.0 million of such government grant funding. To the extent that the Company retains grant revenue in respect of work for which it has also been compensated by the joint venture ("JV Compensation Work"), the remainder of the $3.0 million to be retained by the Company is reduced and the Company records an adjustment in its financial statements to reduce both joint venture losses and contract revenue from the joint venture. Such adjustments were $293 and $134 for the three months ended March 31, 2005 and 2004, respectively, and $2.0 million cumulatively through March 31, 2005. Subsequent to retention in full by the Company of $3.0 million in grant funding related to JV Compensation Work, grant funding from PSMA programs will reduce the funding obligations of the Members equally. The Company is the recipient and obligor under the PSMA-related government grants and activity under those grants is reflected in the Company's financial statements. In the event that the Members do not reach agreement on a work plan and budget for 2005, the ability of the JV to benefit from those grants, and the Company's revenue from those grants, may be adversely affected.

Contract research and development revenue recognized by the Company related to services provided to the JV may vary in the future due to potential future funding limitations on the part of the Members, disagreements between the Members regarding JV funding or operations, the extent to which the JV requests Progenics to perform research and development under the terms of a new Services Agreement or other form of agreement between the Members with respect to such services.

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (continued)
(amounts in thousands, except share and per share amounts or unless otherwise noted)

The Company accounts for its investment in the JV in accordance with the equity method of accounting. Selected financial statement data of the JV are as follows:

Balance Sheet Data	**March 31, 2005**	**December 31, 2004**
Cash	$ 644	
Prepaid expenses	40	$ 12
Total assets	$ 684	$ 12
Accounts payable to Progenics, a related party	$ 744	$ 189
Accounts payable to Cytogen, a related party	53	4
Accounts payable and accrued expenses	692	629
Total liabilities	1,489	822
Stockholders' (deficit)	(805)	(810)
Total liabilities and stockholders' (deficit)	$ 684	$ 12

Statement of Operations Data:	**For the Three Months Ended March 31,**	
	2005	**2004**
Interest income	$ 1	$ 3
Total expenses (1)	997	1,621
Net loss	$ (996)	$ (1,618)

(1) Includes research and development services performed by the Company during the three months ended March 31, 2005 and 2004. During the three months ended March 31, 2005, the JV changed its estimate of certain legal expenses, which had been accrued at December 31, 2004, from $255 to $17.

8. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended March 31, 2005 and 2004, the components of comprehensive loss are:

	Three Months Ended March 31,	
	2005	**2004**
Net loss	$ (13,194)	$ (10,225)

Change in net unrealized gain (loss) on marketable securities		9
Comprehensive loss	$ (13,194)	$ (10,216)

PROGENICS PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (continued)
(amounts in thousands, except share and per share amounts or unless otherwise noted)

9. Commitments and Contingencies

In the ordinary course of its business, the Company enters into agreements with third parties that include indemnification provisions which, in its judgment, are normal and customary for companies in its industry sector. These agreements are typically with business partners, clinical sites and suppliers. Pursuant to these agreements, the Company generally agrees to indemnify, hold harmless and reimburse the indemnified parties for losses suffered or incurred by the indemnified parties with respect to the Company's products or product candidates, use of such products or other actions taken or omitted by the Company. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is not limited. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of liabilities relating to these provisions is minimal. Accordingly, the Company has no liabilities recorded for these provisions as of March 31, 2005.

10. Impact of Recently Issued Accounting Standards

In December 2004, the Financial Accounting Standards Board (the "FASB") issued Statement No. 123 (revised 2004) "Share-Based Payment"("SFAS 123R"), which is a revision of FASB Statement No.123, "Accounting for Stock Based Compensation" ("SFAS 123"). SFAS 123R supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and amends FASB Statement No. 95, "Statement of Cash Flows". SFAS 123R requires all share-based payments to employees, including grants of employee stock options and restricted stock, and purchases of common stock under the Company's Employee Stock Purchase Plans, if compensatory, as defined, to be recognized in the financial statements based on their fair values. The standard allows three alternative transition methods for public companies: modified prospective application; modified retrospective application with restatement of prior interim periods in the year of adoption; and modified retroactive application with restatement of all prior financial statements to include the same amounts that were previously included in pro forma disclosures. Historically, in accordance with SFAS 123 and Statement of Financial Accounting Standards No.148 "Accounting for Stock-Based Compensation-Transition and Disclosure" ("SFAS 148"), the Company had elected to follow the disclosure-only provisions of Statement No.123 and, accordingly, accounted for share-based compensation under the recognition and measurement principles of APB 25 and related interpretations. Under APB 25, when stock options are issued to employees with an exercise price equal to or greater than the market price of the underlying stock price on the date of grant, no compensation expense is recognized in the financial statements and pro forma compensation expense in accordance with FAS 123 is only disclosed in the footnotes to the financial statements. The Company intends to adopt SFAS 123R on January 1, 2006 using the modified prospective application and the Black-Scholes option pricing model to calculate the fair value of option awards. The Company has not yet determined the impact that SFAS 123R will have on its results of operations, financial position and cash flows.

On March 29, 2005, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 107 ("SAB 107"), which expresses views of the SEC staff regarding the interaction between SFAS 123R and certain SEC rules and regulations and provide the SEC staff's views regarding the valuation of share-based payment arrangements for public companies. In particular, SAB 107 provides guidance related to share-based payment transactions with nonemployees, the transition from nonpublic to public entity status, valuation methods (including assumptions such as expected volatility and expected term), the accounting for certain redeemable financial instruments issued under share-based payment arrangements, the classification of compensation expense, non-GAAP financial measures, first-time adoption of SFAS 123R in an interim period, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123R, the modification of employee share options prior to adoption of SFAS 123R and disclosures in Management's Discussion and Analysis subsequent to adoption of SFAS 123R. As noted above, the Company will adopt SFAS 123R on January 1, 2006 and has changed its estimates of expected term and the related period over which expected volatility is calculated, in accordance with SAB 107, effective January 1, 2005. Those revised assumptions will be used by the Company in the Black-Scholes option pricing model, to value share-based awards granted to employees, for the calculation of pro forma net loss and pro forma net loss per share amounts during 2005, in accordance with SFAS 123. The Company will continue to use those revised assumptions upon adoption of SFAS 123R and will implement other aspects of SAB 107 related to presentation and disclosure requirements under SFAS 123R beginning on January 1, 2006.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Special Note Regarding Forward-Looking Statements

Certain statements in this Quarterly Report on Form 10-Q constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Included in these forward-looking statements are statements regarding our expectations for beginning or completing clinical trails, submitting to regulatory authorities applications for marketing approvals for our product candidates, raising additional capital and reducing our operating costs if we cannot raise additional funds. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company, or industry results, to be materially different from any expected future results, performance or achievements expressed or implied by such forward-looking statements. These factors include, among others, the risk that we will not be able to obtain funding necessary to conduct our operations, the uncertainties associated with product development, the risk that clinical trials will not commence, proceed or be completed as planned, the risk that our products will not receive marketing approval from regulators, the risks and uncertainties associated with the dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of our failure to have satisfied performance milestones, the risk that products that appear promising in early clinical trials do not demonstrate efficacy in larger scale clinical trials, the risk that we may not be able to manufacture commercial quantities of our products, the risk that our products, if approved for marketing, do not gain market acceptance sufficient to justify development and commercialization costs, the uncertainty of future profitability and other factors set forth more fully in this Form 10-Q, including those described under the caption "Risk Factors," and other periodic filings with the Securities and Exchange Commission, to which investors are referred for further information.

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this Form 10-Q as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Overview

General. We are a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. We commenced principal operations in late 1988, and since that time we have been engaged primarily in research and development efforts, development of our manufacturing capabilities, establishment of corporate collaborations and raising capital. We do not currently have any commercial products. In order to commercialize the principal products that we have under development, we will need to address a number of technological and clinical challenges and comply with comprehensive regulatory requirements. Accordingly, we cannot predict the amount of funds that we will require, or the length of time that will pass, before we receive significant revenues from sales of any of our products. We may never achieve significant product sales.

Our most advanced product candidate and likeliest source of product revenue is methylnaltrexone ("MNTX"). We are conducting a broad clinical development program for MNTX in several settings involving symptom management and supportive care. It is likely that we will need to complete successfully both of our two phase 3 clinical trials of MNTX, in which we are evaluating MNTX as a treatment for opioid-induced constipation in patients with advanced medical illness, in order to obtain regulatory approval to market MNTX. We completed patient enrollment in the first of these trials, which we call the 301 trial, in the fourth quarter of 2004 and subsequently announced positive top-line results. We anticipate completion of patient enrollment in the second trial, which we call the 302 trial, in the summer of 2005. Assuming we accomplish this objective and the data are positive, we could submit with the U.S. Food and Drug Administration ("FDA") a New Drug Application ("NDA") for marketing approval for MNTX for the treatment of opioid-induced constipation in patients with advanced medical illness between late December 2005 and March 2006. We expect that it would take at least six months for the FDA to act on our application.

We are also developing MNTX for the management of post-operative bowel dysfunction, a serious paralysis of the gastrointestinal tract. We have completed a Phase 2 clinical trial of MNTX for this indication. We completed enrollment for the trial, which we call the 203 trial, in the fourth quarter of 2004 and announced positive top-line results in January 2005. We plan to complete a more in-depth analysis of the data and meet with the FDA in 2005 to discuss designing a phase 3 clinical program. We are also developing oral MNTX for the treatment of opioid-induced constipation in patients with chronic pain and have completed phase 1 clinical trials of oral MNTX in healthy volunteers. We plan to initiate in 2005 phase 2 clinical studies of oral MNTX in chronic pain patients who experience opioid-induced constipation.

In the area of HIV infection, we are developing viral entry inhibitors, which are molecules designed to inhibit the virus' ability to enter certain types of immune system cells. HIV is the virus that causes AIDS. We are conducting a phase 1 study in healthy volunteers of PRO 140, a monoclonal antibody designed to target the HIV co-receptor CCR5. Receptors and co-receptors are structures on the surface of a cell to which a virus must bind in order to infect the cell. We expect to complete enrollment of phase 1 clinical testing of PRO 140 in mid-2005. We have open for enrollment a multi-dose phase 2 clinical trial of PRO 542, a genetically engineered molecule designed to neutralize HIV. We plan to make a decision in the second half of 2005 regarding the ongoing feasibility of our PRO 542 HIV program after reviewing the then-available data from the phase 2 clinical trial in the context of data regarding PRO 140, which targets the same disease.

In addition, we are developing immunotherapies for prostate cancer, including monoclonal antibodies directed against prostate-specific membrane antigen ("PSMA"), a protein found on the surface of prostate cancer cells. We are also developing vaccines designed to stimulate an immune response to PSMA. Our PSMA programs are conducted through PSMA Development Company LLC, our joint venture with Cytogen Corporation (the "JV"). We are also studying a cancer vaccine, GMK, in phase 3 clinical trials for the treatment of malignant melanoma.

The statements above as to our expectations for achieving various milestones are forward-looking statements. There are a variety of factors that may prevent us from achieving these milestones within the timeframes suggested, or at all, including a continuation in delays we have experienced in the past in enrolling patients, the inherent uncertainties associated with seeking marketing approvals from the FDA and the other factors described herein under the caption "Risk Factors."

Our sources of revenues through March 31, 2005 have been payments under our former collaboration agreements, from the JV, from research grants and contracts related to our cancer and HIV programs and from interest income. To date, our product sales have consisted solely of limited revenues from the sale of research reagents. We expect that sales of research reagents in the future will not significantly increase over current levels.

A majority of our expenditures to date have been for research and development activities. We expect that our research and development expenses will increase significantly as our programs progress and we make filings with regulators for approval to market our product candidates.

With the exception of the years ended December 31, 1997 and 1998, we have had recurring losses and had, at March 31, 2005, an accumulated deficit of approximately $132.5 million. At March 31, 2005, we had cash, cash equivalents and marketable securities, including non-current portion, totaling $23.6 million. On April 6, 2005, we received net proceeds of $29.4 million from a public offering of 2.0 million shares of our common stock.. We expect that cash, cash equivalents and marketable securities on hand at March 31, 2005, together with the funds raised in our recent public offering, will be sufficient to fund operations at current levels through mid-2006. We would, however, expect to raise additional funds, or implement significant cost-saving measures, by the end of 2005. During the three-month period ended March 31, 2005, we had a net loss of $13.2 million and used cash in operating activities of $10.0 million. Other than potential revenues from MNTX, which could occur as early as late 2006, we do not anticipate generating significant recurring revenues, from product sales or otherwise, in the near term, and we expect our expenses to increase. Consequently, we will require significant additional external funding to continue our operations at their current levels in the future **.** Such funding may be derived from one or more collaboration or licensing agreements with pharmaceutical or other companies or from the sale of our common stock or other securities to investors.

We have the ability to make cost-saving changes in our operations in the event that we are unable to secure additional funding. Such changes would likely include curtailing significantly one or more of our product development programs and engaging in other cost containment initiatives.

Joint Venture with Cytogen Corporation. We have a 50% interest in our joint venture with Cytogen Corporation. The joint venture's research and development programs and other operations are conducted on its behalf by us, Cytogen and third party providers. We and Cytogen are compensated by the joint venture for our services provided to the joint venture and are reimbursed for costs we pay on its behalf. We were required to fund the first $3.0 million of the joint venture's research and development costs. Prior to reaching $3.0 million of such costs, we recognized reimbursements on a net basis and did not recognize any revenue from the joint venture. During the fourth quarter of 2001, we surpassed the $3.0 million threshold, at which time we began recognizing revenue for services and costs being provided to and paid by the joint venture. Our revenues from the joint venture do not result in significant net cash flows to us, since they are relatively minor in comparison to our expenses and because they are offset in part by capital contributions that we must make to the joint venture.

From June 1999 through January 2004, our services to the joint venture were provided pursuant to the terms of a services agreement. This services agreement, as extended, expired effective January 31, 2004. Although both parties have continued to provide services to the joint venture subsequent to January 2004 (and have been compensated for these services), we and Cytogen have not yet agreed upon the terms of a replacement services agreement. The level of future revenues we derive from the joint venture will depend on the nature and amount of research and development services requested of us by the joint venture as well as the future financial position of the joint venture, which depends on the ability of the Members to reach agreement as to a work plan and budget for each annual period.

Our and Cytogen's respective levels of commitment to fund the joint venture is based on an annual budget and work plan that are developed by the parties. The budget is intended to provide for sufficient funds to conduct the research and development projects specified in the work plan for the then-current year. We have in the past experienced delays in reaching agreement with Cytogen regarding budget issues and strategic and operational matters relating to the joint venture. At March 31, 2005, the joint venture had no approved 2005 budget or work plan because we and Cytogen had not yet reached agreement with respect to a number of matters relating to the joint venture. However, the Members have approved the JV's expenses for the quarter ended March 31, 2005 and have both the intent and ability to fund those expenses. The Members are in discussions to finalize a work plan and budget for the remainder of the year ending December 31, 2005. However, they may not succeed in doing so.

According to the joint venture agreement, we may directly pursue and obtain government grants directed to the conduct of research utilizing PSMA related technologies. In consideration of our initial incremental capital contribution of $3.0 million of joint venture research expenditures, we may retain $3.0 million of such government grant funding. To the extent that we retain grant revenue in respect of work for which it has also been compensated by the joint venture ("JV Compensation Work"), the remainder of the $3.0 million to be retained by us is reduced and we record an adjustment in our financial statements to reduce both joint venture losses and contract revenue from the joint venture. Such adjustments were $293 and $134 for the three months ended March 31, 2005 and 2004, respectively, and $2.0 million cumulatively through March 31, 2005. Subsequent to our retention in full of $3.0 million in grant funding related to JV Compensation Work, grant funding from PSMA programs will reduce the funding obligations of the Members equally. We are the recipient and obligor under the PSMA-related government grants and activity under those grants is reflected in our financial statements. In the event that the Members do not reach agreement on a work plan and budget for 2005, the ability of the JV to benefit from those grants, and our revenue from those grants, may be adversely affected.

Results of Operations **(amounts in thousands)**

Three Months Ended March 31, 2004 and 2005

Revenues:

We recognized $557 and $440 of revenue for research and development services performed for the joint venture during the three months ended March 31, 2004 and 2005, respectively. Proceeds received from grants related to the joint venture and for which we have also been compensated by the joint venture for services provided were $134 in the 2004 period and $293 in the 2005 period. As described above, we have reflected in the accompanying financial statements adjustments to decrease both joint venture losses and contract revenue from the joint venture in respect of such amounts.

Revenues from research grants and contracts increased from $1,186 in the three month period ended March 31, 2004 to $2,145 in the corresponding period in 2005. The increase resulted from the funding of a greater number of grants in the 2005 period, some of which allowed greater spending limits. Additionally, in September 2003, we were awarded a contract by the National Institutes of Health (the "NIH Contract"). The NIH Contract provides for up to $28,600 in funding to us over five years for preclinical research, development and early clinical testing of a vaccine designed to prevent HIV from infecting individuals exposed to the virus. Our scientists are the principal investigators under the contract and head the vaccine development effort. Existing academic collaborators of ours head the vaccine design and animal testing core groups under a subcontract. A total of approximately $3,700 is earmarked under the NIH Contract to fund such subcontracts. Funding under the NIH Contract is subject to compliance with its terms, and the payment of an aggregate of $1,600 in fees (of which $90 had been recognized as revenue as of March 31, 2005) is subject to achievement of specified milestones.

As described below (see "Critical Accounting Policies"), effective January 1, 2005, we have changed our method of recognizing revenue from research collaborations, the JV and government grants and contracts to the Substantive Milestone Method. We do not expect that this change in accounting method will result in a significant difference in the amount of revenue recognized in any period from the JV or government grants and contracts. However, in the event that we enter into one or more collaborations with pharmaceutical companies, the amount of upfront and milestone payments that we receive from those collaborations may be recognized as revenue in periods differently from that under our prior method of revenue recognition.

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Expenses:

Research and development expenses include scientific labor, supplies, facility costs, clinical trial costs, and product manufacturing costs. A major portion of our spending has been, and we expect will continue to be, associated with MNTX. Research and development expenses increased $3,725 from $8,374 in the three months ended March 31, 2004 to $12,099 in the corresponding period in 2005. During the 2005 period, such expenses consisted of approximately $3,507 of salaries and benefits, $3,643 of clinical trial costs, $3,366 in laboratory supplies, $814 for operating expenses, including rent and other facilities costs, insurance and travel, $219 for contract manufacturing and subcontractors, $441 for consultants, and $109 in license fees.

Increases quarter-over-quarter included:

- $1,931 in clinical trial costs, primarily for MNTX,
- $415 in salaries and benefits related to company-wide compensation increases as well as an increase in headcount from 107 at March 31, 2004 to 109 at March 31, 2005 in the research and development, manufacturing and medical departments,
- $105 in consultants, of which $88 was related to MNTX and $17 was related to HIV, GMK and other projects,
- $1,658 in laboratory supplies for MNTX,
- $34 in contract manufacturing and subcontractor costs related to MNTX, and
- $76 in license fees primarily related to our HIV programs.

These increases were offset in part by decreases of:

- $27 in contract manufacturing and subcontractor costs related to HIV and other projects,
- $100 in laboratory supplies for HIV, GMK program and other non- MNTX programs, and
- $367 in operating expenses.

We expect significant increases in research and development expenses related to MNTX as the clinical programs expand and progress. These expenses would be reduced if we enter into a collaboration for MNTX in which the collaborator assumes financial responsibility for some or all of the future development of MNTX, or if we choose not to advance all of our MNTX programs. Spending in other programs is expected to remain relatively stable.

General and administrative expenses increased from $2,815 in 2004 to $3,143 in 2005. The $328 increase was principally due to an increase of:

- $272 in salaries and benefits related to an increase in administrative headcount and salary increases, and
- $190 in legal and consulting fees

These increases were offset by decreases of:

- $103 in operating expenses including rent, insurance, travel and office supplies, and
- $35 in franchise, sales and other corporate taxes.

We expect general and administrative expenses to remain relatively stable during the remainder of 2005 due to the expected decrease in professional fees related to compliance with requirements concerning internal controls over financial reporting offset by an increase in operating expenses related to an increase in headcount.

Loss in joint venture decreased from $675 in the three months ended March 31, 2004 to $205 in the corresponding period in 2005 due primarily to higher research and development expenses in the 2005 period, offset by license fees in the 2004 period which did not recur in the 2005 period. As further described above, we recognized $134 and $293 in the three months ended March 31,2004 and 2005, respectively, of payments received from the NIH as a reduction to joint venture losses and contract revenue from the joint venture. For the year ending December 31, 2005, the magnitude of the loss in joint venture will depend on the budget agreed to by the Members for the remainder of 2005. At March 31, 2005, the Members had approved the JV expenses for the quarter ended March 31, 2005 and had the intention and ability to fund those expenses. However, agreement on a work plan and budget for the remainder of 2005 had not been reached and discussions to that end

were in progress (see “Liquidity and Capital Resources”).

Depreciation and amortization increased from $326 in the three months ended March 31, 2004 to $482 in the corresponding period in 2005 as we purchased capital assets and made leasehold improvements in the 2005 period to increase our manufacturing capacity.

Other income:

Interest income decreased from $217 in the three months ended March 31, 2004 to $146 in the corresponding period in 2005 as cash available for investing decreased quarter-over-quarter and amortization of premiums on our marketable securities decreased from $202 in the 2004 period to $77 in the 2005 period.

Net loss:

Our net loss was $10,225 for the three months ended March 31,2004 compared to a net loss of $13,194 in the corresponding period in 2005.

Liquidity and Capital Resources

We have to date generated no meaningful amounts of recurring revenue, and consequently we have relied principally on external funding to finance our operations. We have funded our operations since inception primarily through private placements of equity securities, payments received under collaboration agreements, four public offerings of common stock, funding under government research grants and contracts, interest on investments, the proceeds from the exercise of outstanding options and warrants and the purchase of our common stock under our employee stock purchase plans.

In 2004, we filed a Form S-3 shelf registration with the SEC which permits us, from time to time, to offer and sell up to an aggregate of $60 million of our common stock. In April 2005, pursuant to our shelf registration, we completed our fourth public offering of common stock which provided us with $29.4 million in net proceeds from the sale of 2.0 million shares.

At March 31, 2005 (prior to completion of the public offering of common stock described above), we had cash, cash equivalents and marketable securities, including non-current portion, totaling $23.6 million compared with $31.2 million at December 31, 2004. Net cash used in operating activities for the three months ended March 31, 2005 was $10.0 million compared with $9.5 million for the same period in 2004. The increase of $0.5 million resulted primarily from an increase in our net loss of $3.0 million to $13.2 million for the three months ended March 31, 2005, mostly due to increased research and development activity in 2005, impacted by (i) an increase of $156,000 in depreciation and amortization resulting from the purchase of fixed assets and leasehold improvements for our expanded manufacturing capacity, (ii) a decrease of $125,000 in amortization of premiums on marketable securities due to changes in the composition of our portfolio, (iii) an increase of $193,000 of amortization of unearned compensation resulting from the issuance to employees of restricted stock in 2004 and 2005, (iv) a decrease in loss in JV of $311,000 resulting from a license payment that was due in the first quarter of 2004 and not due in the corresponding period in 2005, which partially offset an increase in research and development activity in the 2005 period, (v) and a decrease of $450,000 of capital contributions to JV because a budget had not been approved by the Members during the first quarter of 2005. Capital contributions to the JV during the first quarter of 2005 were used to fund the obligations outstanding related to work performed in 2004 under the approved 2004 budget and work plan. Additionally, the net impact of our changes in assets and liabilities in the three months ended March 31, 2005 was $2.3 million of cash provided by operating activities, primarily due to an increase in accounts payable and accrued expenses, resulting mainly from increased costs of clinical trials, and a decrease in accounts receivable. For the three months ended March 31, 2004, the net impact of our changes in assets and liabilities was $204,000 of cash provided by operating activities due primarily to a decrease in prepaid insurance costs and an increase in amounts due from the joint venture.

Net cash provided by investing activities was $7.8 million for the three months ended March 31, 2005 compared with $4.0 million for the same period in 2004. Net cash provided by investing activities for the three month period ended March 31, 2005 resulted primarily from the sale of $13.5 million of marketable securities offset by the purchase of $5.4 million of marketable securities and the purchase of $0.3 million of fixed assets including capital equipment and leasehold improvements as we acquired and built out additional manufacturing space.

Net cash provided by financing activities was $2.8 million for the three months ended March 31, 2005 as compared with $1.9 million for the same period in 2004. The net cash provided by financing activities for both periods reflects the exercise of stock options under our Employee Stock Option Plans and the sale of common stock under our Employee Stock Purchase Plans. During the remainder of 2005, we expect that cash received from exercises under such plans will increase due to increased headcount.

Under the terms of our joint venture with Cytogen, we are required to make capital contributions to fund 50% of the spending on the PSMA projects. We contributed $0.5 million during the three months ended March 31, 2005, which was used to fund the obligations outstanding related to work performed in 2004 under the approved 2004 budget and work plan. Our and Cytogen's level of commitment to fund the joint venture is based on an annual budget that is developed by the parties. At March 31, 2005, the joint venture had no approved 2005 budget or work plan because we and Cytogen had not yet reached agreement with respect to a number of matters relating to the joint venture. However, the Members had approved the JV's expenses for the quarter ended March 31, 2005 and have both the intent and ability to fund those expenses. The Members are in discussions to finalize a work plan and budget for the remainder of the year ending December 31, 2005. However, they may not be successful in doing so.

For the three months ended March 31, 2005, we recognized approximately $440,000 of contract research and development revenue for services performed on behalf of the joint venture. Our revenues from the joint venture do not result in significant net cash flows to us, since they are relatively minor in comparison to our expenses and because they are offset in part by capital contributions that we must make to the joint venture.

Our total expenses for research and development from inception through March 31, 2005 have been approximately $170.2 million. We currently have major research and development programs investigating symptom management and supportive care, HIV-related diseases and cancer. In addition, we are conducting several smaller research projects in the areas of virology and cancer. For various reasons, many of which are outside of our control, including the early stage of certain of our programs, the timing and results of our clinical trials and our dependence in certain instances on third parties, we cannot estimate the total remaining costs to be incurred and timing to complete our research and development programs. If we do not enter into a collaboration agreement with respect to MNTX pursuant to which our partner assumes some or all of the financial responsibility for further development, and we proceed with each of our MNTX programs, we expect that our spending on MNTX will increase significantly during the remainder of 2005. We expect that spending on other programs will remain relatively stable in 2005.

For the three month periods ended March 31, 2004 and 2005, research and development costs incurred were as follows (see "—Results of Operations—Expenses"):

	2004	2005
	(in millions)	
MNTX	$ 3.2	$ 8.4
HIV	3.0	1.6
Cancer	1.7	1.6
Other programs	0.5	0.5
Total	$ 8.4	$ 12.1

In September 2003, we were awarded a contract by the National Institutes of Health (the "NIH Contract"). The NIH Contract provides for up to $28.6 million in funding, subject to annual funding approvals, to us over five years for preclinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus. We anticipate that these funds will be used principally in connection with our ProVax HIV vaccine program. Our scientists are the principal investigators under the contract and head the vaccine development effort. Existing academic collaborators of ours head the vaccine design and animal testing core groups under a subcontract. A total of approximately $3.7 million is earmarked under the NIH Contract to fund such subcontracts. Funding under the NIH Contract is subject to compliance with its terms, and the payment of an aggregate of $1.6 million in fees is subject to achievement of specified milestones. Through March 31, 2005, we had recognized revenue of $3.6 million from this contract, including $90,000 for the achievement of a milestone.

Other than currently approved grants and contracts, we have no committed external sources of capital, and other than potential revenues from MNTX, which could occur as early as late 2006, we expect no significant product revenues for a number of years as it will take at least that much time, if ever, to bring our products to the commercial marketing stage.

We anticipate significant increases in expenditures as we continue to expand our research and development activities, particularly in our MNTX programs. Consequently, we will require additional funding to continue our research and product development programs, to conduct preclinical studies and clinical trials, for operating expenses, to pursue regulatory approvals for our product candidates, for the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims, if any, for the cost of product in-licensing and for any possible acquisitions. If we commercialize MNTX or any other product candidate other than with a corporate collaborator, we would also require additional funding to establish manufacturing and marketing capabilities.

Our existing cash, cash equivalents and marketable securities as well as the proceeds of our April 2005 public offering of common stock are sufficient to fund current operations for at least the next 12 months. We would, however, expect to raise additional funds, or implement significant cost-saving measures, by the end of 2005. We are currently in negotiations with potential collaborators for the MNTX programs, and we are seeking to finalize a collaboration agreement in 2005. We expect that such a collaboration arrangement would include up-front license fees or other payments as well as milestone payments. We also expect that a collaborator would assume some or all of the financial responsibility for further clinical development and commercialization of a majority of the MNTX programs. We may also enter into a collaboration agreement with respect to other of our product candidates. We cannot forecast with any degree of certainty, however, which products or indications, if any, will be subject to future collaborative arrangements, or how such arrangements would affect our capital requirements. The consummation of a collaboration agreement would allow us to allocate our current funds to advance other projects.

We may also seek to raise additional capital through the sale of common stock or other securities. In doing so, we may continue to utilize our previously filed shelf registration statement described above. There can be no assurance that we would be able to complete any further securities transactions. We may also seek to fund aspects of our operations through government grants and contracts.

For periods beyond 12 months, we may seek additional financing to fund operations through future offerings of equity or debt securities or agreements with corporate collaborators with respect to the development of our technologies and funding from additional grants and government contracts. Adequate additional funding may not be available to us on acceptable terms or at all. We have the ability to make cost-saving changes in our operations in the event that we are unable to secure additional funding. Such changes would likely include focusing our resources on our late-stage MNTX program, which we believe has the greatest likelihood of generating near-term cash flows, and reducing or eliminating funding to some or all of our other product development programs. We believe that these measures would significantly reduce our operating expenses. The extent to which these changes will be implemented, if at all, will depend upon a variety of factors, including cash in-flows from collaborations, financings or other sources, the extent to which negative cash flows from operations continue and the perceived likelihood of success, and expected costs to completion, of our various product development programs. These steps would likely adversely impact our prospects for product commercialization and, consequently, our prospects for product sales and profitability. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize the future success of our business.

Our funding requirements, both for the next 12 months and beyond, will include required payments under operating leases and licensing and collaboration agreements. The following table summarizes our contractual obligations as of March 31, 2005 for future payments under these agreements:

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	Greater than 5 years
			(in millions)		
Operating leases	$ 5.9	$ 1.6	$ 2.7	$ 1.6	
License and collaboration agreements (1)	23.8	1.5	7.4	2.2	$ 12.7
Total	$ 29.7	$ 3.1	$ 10.1	$ 3.8	$ 12.7

(1) Assumes attainment of milestones covered under each agreement. The timing of the achievement of the related milestones is highly uncertain, and accordingly the actual timing of payments, if any, is likely to vary, perhaps significantly, relative to the timing contemplated by this table. This table does not reflect the payment obligations of our joint venture with Cytogen or payment obligations of the Company to the joint venture since the Members have not reached agreement on a work plan and budget for 2005.

For each of our programs, we periodically assess the scientific progress and merits of the programs to determine if continued research and development is economically viable. For example, we have open for enrollment a multi-dose phase 2 clinical trial of PRO 542, a genetically engineered molecule designed to neutralize HIV. We plan to make a decision in the second half of 2005 regarding the ongoing feasibility of our PRO 542 program after reviewing the then-available data from the phase 2 clinical trial in the context of data regarding PRO 140, which targets the same disease. Certain of our programs have been terminated due to the lack of scientific progress and lack of prospects for ultimate commercialization. Because of the uncertainties associated with research and development of these programs, the duration and completion costs of our research and development projects are difficult to estimate and are subject to considerable variation. Our inability to complete our research and development projects in a timely manner or our failure to enter into collaborative agreements could significantly increase our capital requirements and adversely impact our liquidity.

Our cash requirements may vary materially from those now planned because of results of research and development and product testing, changes in existing relationships with, or new relationships with, licensees, licensors or other collaborators, changes in the focus and direction of our research and development programs, competitive and technological advances, the cost of filing, prosecuting, defending and enforcing patent claims, the regulatory approval process, manufacturing and marketing and other costs associated with the commercialization of products following receipt of regulatory approvals and other factors.

The above discussion contains forward-looking statements based on our current operating plan and the assumptions on which it relies. There could be changes that would consume our assets earlier than planned.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity.

Critical Accounting Policies

Revenue Recognition

During the quarters ended March 31, 2005 and 2004, we recognized revenue from PSMA Development Company LLC (the “JV”) (a related party), our joint venture with Cytogen Corporation, for contract research and development; from government research grants and contracts from the National Institutes of Health (the “NIH”), which are used to subsidize certain of the our research projects (“Projects”); and from the sale of research reagents.

Effective January 1, 2005, we elected to change the method we use to recognize revenue under SAB 104 for payments received under research and development collaboration agreements that contain substantive at-risk milestone payments. There was no cumulative effect of this change in accounting principle because we do not currently have any of these contracts. Under the new method, non-refundable up-front license payments received from collaborators, not tied to achieving a specific performance milestone, are recognized as revenue ratably over the period during which we expect to perform services, because no separate earnings process has been completed. Payments for research and development activities are recognized as revenue as we earn the related services. Substantive at-risk milestone payments, which are based on our achieving a specific performance milestone, are recognized as revenue when the milestone is achieved and the related payment is due, provided there is no future service obligation on our part associated with that milestone (the “Substantive Milestone Method”). The change in accounting method was made because we believe that it will enhance the comparability of our financial results with those of our peer group companies in the biotechnology industry and because it is expected to better reflect the substance of our collaborative arrangements.

Previously, we had recognized non-refundable fees, including payments for services, up-front licensing fees and milestone payments, as revenue based on the percentage of efforts incurred to date, estimated total efforts to complete, and total expected contract revenue in accordance with EITF Issue No. 91-6, “Revenue Recognition of Long-Term Power Sales Contracts,” with revenue recognized limited to the amount of non-refundable fees received. Depending on the magnitude and timing of milestone payments, revenue may be recognized sooner under the Substantive Milestone Method than it would have been under the EITF 91-6 model.

The accounting change will not affect revenue from NIH grants and contracts, services performed on behalf of the JV, or from product sales.

NIH grant and contract revenue is recognized as efforts are expended and as related subsidized Project costs are incurred. We perform work under the NIH grants and contract on a best-efforts basis. The NIH reimburses us for costs associated with the preclinical research, development and early clinical testing of a prophylactic vaccine designed to prevent HIV from becoming established in uninfected individuals exposed to the virus, as requested by the NIH. Substantive at-risk milestone payments are uncommon in these arrangements, but would be recognized as revenue on the same basis as the Substantive Milestone Method.

Both we and Cytogen are required to fund the JV equally to support ongoing research and development efforts conducted by us on behalf of the JV. We recognize payments for research and development as revenue as services are performed. For the quarters ended March 31, 2005 and 2004, we recognized approximately $0.4 million and $0.6 million, respectively, of contract research and development revenue for services performed on behalf of the JV.

For three months ended March 31, 2005 and 2004, our research grant and contract revenue and contract research and development revenue came exclusively from the NIH and the JV, respectively.

Clinical Trial Expenses

Clinical trial expenses, which are included in research and development expenses, represent obligations resulting from our contracts with various clinical investigators and clinical research organizations in connection with conducting clinical trials for our product candidates. Such costs are expensed based on the expected total number of patients in the trial, the rate at which the patients enter the trial and the period over which the clinical investigators and clinical research organizations are expected to provide services. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates. We expect that clinical trial expenses will increase significantly during the remainder of 2005 as clinical trials progress or are initiated in the MNTX and HIV programs. A collaboration agreement regarding MNTX in which the collaborator assumes some or all of the financial responsibility for further development would mitigate these costs.

Stock-Based Compensation

We have historically prepared our financial statements in accordance with APB Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB No. 25”). In accordance with APB No. 25, generally, we have not recognized compensation expense in connection with the awarding of common stock option grants to employees provided that, as of the grant date, all terms associated with the award are fixed and the fair value of our common stock, as of the grant date, is equal to or less than the exercise price. We recognize compensation expense if the terms of an option grant are not fixed or the quoted market price of our common stock on the grant date is greater than the exercise price. We also recognize compensation expense for performance-based vesting of stock options upon achievement of defined milestones and for restricted stock awards as the restrictions lapse ratably over the related vesting periods. The fair value of options and warrants granted to non-employees for services are included in the financial statements and expensed as they vest.

We intend to adopt Statement of Financial Accounting Standards No. 123 (revised 2004) “Share-Based Payment” (“SFAS 123R”) on January 1, 2006, using the modified prospective application. In anticipation of the adoption of SFAS 123R, we have revised certain assumptions used in the Black-Scholes option pricing model used to value equity-based awards. The estimate of expected term has been increased from 5 years to 6.5 years for all awards granted on or after January 1, 2005, in accordance with the simplified method described in Staff Accounting Bulletin No. 107 for options with five-year graded vesting. The period used to calculate historical volatility of our common stock has also been revised to 6.5 years. The impact of these revisions is expected to increase the amount of compensation expense we recognize as compared to the amount that would have been recognized using the previous estimates.

Impact of Recently Issued Accounting Standards

In December 2004, the Financial Accounting Standards Board (the “FASB”) issued SFAS 123R, which is a revision of FASB Statement No.123, “Accounting for Stock Based Compensation” (SFAS 123”). SFAS 123R supersedes APB Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB 25”), and amends FASB Statement No. 95, “Statement of Cash Flows”. SFAS 123R requires all share-based payments to employees, including grants of employee stock options and restricted stock and purchases of common stock under the Company’s Employee Stock Purchase Plans, if compensatory, as defined, to be recognized in the financial statements based on their fair values. The standard allows three alternative transition methods for public companies: modified prospective application; modified retrospective method with restatement of prior interim periods in the year of adoption; and modified retroactive application with restatement of all prior financial statements to include the same amounts that were previously included in pro forma disclosures. Historically, in accordance with SFAS 123 and Statement of Financial Accounting Standards No.148 “Accounting for Stock-Based Compensation-Transition and Disclosure” (“SFAS 148”), the Company had elected to follow the disclosure-only provisions of Statement No. 123 and, accordingly accounted for share-based compensation under the recognition and measurement principles of APB Opinion No. 25 and related interpretations. Under APB 25, when stock options are issued to employees with an exercise price equal to or greater than the market price of the underlying stock price on the date of grant, no compensation expense is recognized in the financial statements; pro forma compensation expense in accordance with FAS 123 is only disclosed in the footnotes to the financial statements. We intend to adopt SFAS 123R on January 1, 2006 using the modified prospective application and the Black-Scholes option pricing model to calculate the fair value of option awards. We have not yet determined the impact that SFAS 123R will have on our results of operations, financial position and cash flows.

On March 29, 2005, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 107 ("SAB 107"), which expresses views of the SEC staff regarding the interaction between SFAS 123R and certain SEC rules and regulations and provide the SEC staff's views regarding the valuation of share-based payment arrangements for public companies. In particular, SAB 107 provides guidance related to share-based payment transactions with nonemployees, the transition from nonpublic to public entity status, valuation methods (including assumptions such as expected volatility and expected term), the accounting for certain redeemable financial instruments issued under share-based payment arrangements, the classification of compensation expense, non-GAAP financial measures, first-time adoption of SFAS 123R in an interim period, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123R, the modification of employee share options prior to adoption of SFAS 123R and disclosures in Management's Discussion and Analysis subsequent to adoption of SFAS 123R. As noted above, we will adopt SFAS 123R on January 1, 2006 and have changed our estimates of expected term and the related period over which expected volatility is calculated, in accordance with SAB 107, effective January 1, 2005. We will use those revised assumptions in the Black-Scholes option pricing model, to value share-based awards granted to employees, for the calculation of pro forma net loss and pro forma net loss per share amounts during 2005, in accordance with Statement of Financial Accounting Standards No. 123 "Accounting for Stock-Based Compensation". We will continue to use those revised assumptions upon adoption of SFAS 123R and will implement other aspects of SAB 107 related to presentation and disclosure requirements under SFAS 123R beginning on January 1, 2006.

RISK FACTORS

Our business and operations entail a variety of risks and uncertainties, including those described below.

Our product development programs are inherently risky.

We are subject to the risks of failure inherent in the development of product candidates based on new technologies. Our MNTX product candidate, which is designed to reverse certain side effects induced by opioids, is based on a novel method of action that has not yet been proven to be safe or effective. No drug with MNTX's method of action has ever received marketing approval. Additionally, some of our HIV product candidates are designed to be effective by blocking viral entry, and our GMK product candidate is designed to be a therapeutic cancer vaccine. To our knowledge, no drug designed to treat HIV infection by blocking viral entry (with one exception) and no cancer therapeutic vaccine has been approved for marketing in the U.S. Our other research and development programs, and those conducted through our joint venture with Cytogen, involve similarly novel approaches to human therapeutics. Consequently, there is little precedent for the successful commercialization of products based on our technologies. There are a number of technological challenges that we must overcome to complete most of our development efforts. We may not be able to develop successfully any of our products.

If testing does not yield successful results, our products will not be approved.

We will need to obtain regulatory approval before we can market our product candidates. To obtain marketing approval from regulatory authorities, we or our collaborators must demonstrate a product's safety and efficacy through extensive preclinical and clinical testing. Numerous adverse events may arise during, or as a result of, the testing process, including the following:

- the results of preclinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;

- potential products may not have the desired efficacy or may have undesirable side effects or other characteristics that preclude marketing approval or limit their commercial use if approved;

- after reviewing test results, we or our collaborators may abandon projects which we previously believed to be promising; and

- we, our collaborators or regulators may suspend or terminate clinical trials if we or they believe that the participating subjects or patients are being exposed to unacceptable health risks.

Clinical testing is very expensive and can take many years. Results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials. Moreover, many of our products, such as PRO 140 and the PSMA product candidates, are at an early stage of development. The successful commercialization of early stage products will require significant further research, development, testing, approvals by regulators and additional investment. Our products in the research or preclinical development stage may not yield results that would permit or justify clinical testing. Our failure to adequately demonstrate the safety and efficacy of a product under development would delay or prevent marketing approval of the product, which could adversely affect our operating results and credibility.

A setback in our clinical development programs could adversely affect us.

We have several ongoing late-stage clinical trials. We have completed a pivotal phase 3 clinical trial of MNTX for the treatment of opioid-induced constipation in patients with advanced medical illness, and another pivotal study of MNTX for this indication is ongoing. It is likely that we will need to successfully complete both of these trials in order to obtain approval of the FDA to market MNTX. We also have completed a phase 2 clinical trial of intravenous MNTX in patients at risk for post-operative bowel dysfunction and intend to conduct additional clinical trials of oral MNTX in chronic pain patients who experience opioid-induced constipation. If the results of any of these ongoing trials are not satisfactory, or if we encounter problems enrolling patients, clinical trial supply issues or other difficulties, our entire MNTX development program could be adversely affected, resulting in delays in commencing or completing clinical trials or in making our regulatory filing for marketing approval. The need to conduct additional clinical trials or significant revisions to our clinical development plan would lead to delays in our filing for the regulatory approvals necessary to market MNTX. Since MNTX is our most clinically advanced product, a setback of this nature would have a material adverse effect on our stock price and business.

We also have two ongoing pivotal phase 3 clinical trials for GMK. In May 2000, our collaborating research cooperative group in one of these trials, ECOG, recommended to clinical investigators participating in the trial that they discontinue administering GMK, and as a result that trial did not complete patient dosing as contemplated by the initial trial protocol. A second pivotal phase 3 trial for GMK was initiated in May 2001, and at present we do not expect to reach the full enrollment of 1,300 patients until the second half of 2005 and expect to assess the recurrence of cancer and overall survival of the study patients over the next several years. If the results of either of the GMK trials are not satisfactory, we may need to conduct additional clinical trials or abandon our GMK program.

We have open for enrollment a multi-dose phase 2 clinical trial of PRO 542, a genetically engineered molecule designed to neutralize HIV. We plan to make a decision in the second half of 2005 regarding the ongoing feasibility of our PRO 542 program after reviewing the then-available data from the phase 2 clinical trial in the context of data regarding PRO 140, which targets the same disease.

Additionally, if the results of our phase 1 study with PRO 140 or the preclinical and clinical studies involving the PSMA vaccine and antibody candidates are not satisfactory, we would need to reconfigure our clinical trial programs to conduct additional trials or abandon the program involved.

We have a history of operating losses, and we may never be profitable.

We have incurred substantial losses since our inception. As of March 31, 2005, we had an accumulated deficit of approximately $132.5 million. We have derived no significant revenues from product sales or royalties. We do not expect to achieve significant product sales or royalty revenue for a number of years, if ever, other than potential revenues from MNTX, which could occur as early as late 2006. We expect to incur additional operating losses in the future, which could increase significantly as we expand our clinical trial programs and other product development efforts.

Our ability to achieve and sustain profitability is dependent in part on obtaining regulatory approval to market our products and then commercializing, either alone or with others, our products. We may not be able to develop and commercialize products. Moreover, our operations may not be profitable even if any of our products under development are commercialized.

We are likely to need additional financing, but our access to capital funding is uncertain.

As of March 31, 2005, we had cash, cash equivalents and marketable securities, including non-current portion, totaling $23.6 million. During the quarter then ended, we had a net loss of $13.2 million and used cash in operating activities of $10.0 million. On April 6, 2005, we received net proceeds of $29.4 million from the sale of 2.0 million shares of our common stock. We anticipate significant increases in expenditures as we continue to expand our research and development activities, particularly in our MNTX programs. Consequently, we will need substantial additional funds to conduct product development activities. We intend to seek additional external funding, most likely through collaborative agreements, or other license or sale transactions, with one or more pharmaceutical companies regarding MNTX or other products, through the issuance and sale of securities or through additional government grants or contracts. We cannot predict with any certainty when we will need additional funds or how much we will need or if additional funds will be available to us. Our need for future funding will depend on numerous factors, many of which are outside our control.

Our access to capital funding is uncertain. We do not have committed external sources of funding for most of our drug development projects, and we may not be able to obtain additional funds on acceptable terms, or at all. We have the ability to make cost-saving changes in our operations in the event that we are unable to secure additional funding in the near term. Such changes would include focusing our resources on our late-stage MNTX program, which we believe has the greatest likelihood of generating near-term cash flows, and reducing or eliminating funding to some or all of our other product development programs. There are other cost-containment initiatives that we could implement. These steps would likely adversely impact our prospects for product commercialization and, consequently, our prospects for product sales and profitability. We might also need to sell or license our product candidates or other technologies on terms that are not favorable to us, which could also adversely affect our prospects for profitability. Our inability to raise additional capital on terms reasonably acceptable to us would seriously jeopardize the future success of our business.

If we raise funds by issuing and selling securities, it may be on terms that are not favorable to our existing stockholders. If we raise additional funds by selling equity securities, our current stockholders will be diluted, and new investors could have rights superior to our existing stockholders. If we raise funds by selling debt securities, we could be subject to restrictive covenants and significant repayment obligations.

Our clinical trials could take longer than we expect.

Although for planning purposes we forecast the commencement and completion of clinical trials, and have included or incorporated by reference many of those forecasts in this report and in other public disclosures, the actual timing of these events can vary dramatically. For example, we have experienced delays in our MNTX clinical development program as a result of slower than anticipated patient enrollment. These delays may recur. Our second pivotal phase 3 clinical trial of MNTX is being conducted in the hospice setting, where historically there have been limited resources, infrastructure and experienced personnel available to conduct such studies, which can lead to delays. Delays can also be caused by, among other things,

- deaths or other adverse medical events involving patients or subjects in our clinical trials,
- regulatory or patent issues,
- interim or final results of ongoing clinical trials,
- failure to enroll clinical sites as expected,
- scheduling conflicts with participating clinicians and clinical institutions and
- manufacturing problems.

In addition, we may need to delay or suspend our clinical trials if we are unable to obtain additional funding when needed. Also, our clinical programs involving our joint venture with Cytogen could be delayed by disagreements between Cytogen and us concerning funding development programs or other matters. At March 31, 2005, the joint venture had no approved 2005 budget or work plan because we and Cytogen had not yet reached agreement with respect to a number of matters relating to the joint venture and we may never reach agreement. Clinical trials involving our product candidates may not commence or be completed as forecasted.

Moreover, we have limited experience in conducting clinical trials, and we rely on others to conduct, supervise or monitor some or all aspects of some of our clinical trials. In addition, certain clinical trials for our products may be conducted by government-sponsored agencies, and consequently will be dependent on governmental participation and funding. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

As a result of these and other factors, our clinical trials may not commence or be completed as we expect or may not be conducted successfully, in which event investors' confidence in our ability to develop products may be impaired and our stock price may decline.

We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated fines and delays.

We and our products are subject to comprehensive regulation by the FDA in the U.S. and by comparable authorities in other countries. These national agencies and other federal, state and local entities regulate, among other things, the preclinical and clinical testing, safety, approval, manufacture, labeling, marketing, export, storage, record keeping, advertising and promotion of pharmaceutical products. If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to forced removal of a product from the market, product seizure, civil and criminal penalties and other adverse consequences.

We do not yet have, and may never obtain, the regulatory approvals we need to market our products.

None of our products has been approved by applicable regulatory authorities for marketing. The process of obtaining FDA and foreign regulatory approvals often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. We have had only limited experience in filing and pursuing applications and other submissions necessary to gain marketing approvals. We may not obtain marketing approval from the FDA or any other regulatory authority for any of our products under development.

Even if we obtain regulatory approval to market a product:

- we might not obtain labeling claims necessary to make the product commercially viable (in general, labeling claims define the medical conditions for which a drug product may be marketed, and are therefore very important to the commercial success of a product);
- we may be required to undertake post-marketing trials to verify the product's efficacy or safety;
- we or others may identify side effects after the product is on the market, or we may experience manufacturing problems, either of which could result in subsequent withdrawal of marketing approval, reformulation of the product, additional preclinical testing or clinical trials, changes in labeling of the product or the need for additional marketing applications; and
- we will be subject to ongoing FDA obligations and continuous regulatory review.

If we fail to receive marketing approval for our products or lose previously received approvals, our financial results would be adversely affected.

Even if we obtain marketing approval for our products, they might not be accepted in the marketplace.

The commercial success of our products will depend upon their acceptance by the medical community and third party payors as clinically useful, cost effective and safe. If healthcare providers believe that patients can be managed adequately with alternative, currently available therapies, they may not prescribe our products, especially if the alternative therapies are viewed as more effective, as having a better safety or tolerability profile, as being more convenient to the patient or healthcare providers or as being less expensive. For pharmaceuticals administered in an institutional setting, the ability of the institution to be adequately reimbursed could also play a significant role in demand for our products. Even if our products obtain marketing approval, they may not achieve market acceptance. If any of our products do not achieve market acceptance, we will likely lose our entire investment in that product.

Marketplace acceptance will depend in part on competition in our industry, which is intense.

The extent to which any of our products achieves market acceptance will depend on competitive factors. Competition in our industry is intense, and it is accentuated by the rapid pace of technological development. There are products currently in the market that will compete with the products that we are developing, including chemotherapy drugs for treating cancer and AIDS drugs. As described below, Adolor Corporation is developing a drug that would compete with MNTX. Many of our competitors have substantially greater research and development capabilities and experience and greater manufacturing, marketing, financial and managerial resources than we do. These competitors may develop products that are superior to those we are developing and render our products or technologies non-competitive or obsolete. If our product candidates receive marketing approval but cannot compete effectively in the marketplace, our operating results and financial position would suffer.

One or more competitors developing an opioid antagonist may reach the market ahead of us and adversely affect the market potential for MNTX.

We are aware that Adolor Corporation, in collaboration with Glaxo Group Limited, or Glaxo, a subsidiary of GlaxoSmithKline plc, is developing an opioid antagonist, Entereg™ (alvimopan), for post-operative ileus, which has completed phase 3 clinical trials, and for opioid bowel dysfunction and chronic constipation, which have completed phase 2 trials. Post-operative ileus is a condition similar to post-operative bowel dysfunction, a condition for which we are developing MNTX. Entereg is further along in the clinical development process than MNTX and is the subject of an application pending with the FDA for marketing approval in the U.S. Additionally, it has been reported that a European specialty pharmaceutical company is in clinical development of an oral formulation of methylnaltrexone for use in opioid-induced constipation. If either of these products reaches the market before our MNTX product, it could achieve a significant competitive advantage relative to our product. In any event, the considerable marketing and sales capabilities of Glaxo may impair our ability to penetrate the market.

Disputes with Cytogen could delay or halt our PSMA programs.

Our research and development programs relating to vaccine and antibody immunotherapeutics based on PSMA are conducted through a joint venture between Cytogen Corporation and us. This is a 50/50 joint venture, meaning that our ownership rights in the programs, funding obligations and governance rights generally are equal. As a result, for the joint venture to operate efficiently, and for the research and development programs to be adequately funded and staffed and productive, we and Cytogen must be in agreement on strategic and operational matters. There is a significant risk that, as a result of differing views and priorities, there will be occasions when we do not agree on various matters, as is the case currently.

Our level of commitment to fund the PSMA joint venture and that of our joint venture partner, Cytogen, is based upon an annual budget and work plan that are developed and approved by the parties. We have in the past experienced delays in reaching agreement with Cytogen regarding annual budget issues and strategic and operational matters relating to the joint venture. At March 31, 2005, the joint venture had no approved 2005 budget or work plan because we and Cytogen had not yet reached agreement with respect to a number of matters relating to the joint venture. However, the Members had approved the JV's expenses for the quarter ended March 31, 2005 and have both the intention and ability to fund those expenses. The Members are in discussions to finalize a work plan and budget for the remainder of the year ending December 31, 2005. If we do not reach an agreement regarding the budget and work plan for 2005 or future years, we would likely experience delays in advancing the PSMA programs and may need to dissolve the joint venture and abandon the PSMA programs being conducted by the joint venture. We may not reach an agreement with Cytogen on these matters.

If we are unable to negotiate collaborative agreements, our cash burn rate could increase and our rate of product development could decrease.

We intend to pursue new collaborative agreements. For instance, we are currently in discussions with potential strategic collaborators for MNTX. However, we may not be successful in negotiating additional collaborative arrangements. If we do not enter into new collaborative arrangements, we would have to devote more of our resources to clinical product development and product-launch activities, and our cash burn rate would increase or we would need to take steps to reduce our rate of product development.

If we do not remedy our failure to achieve milestones or satisfy conditions regarding some of our product candidates, we may not maintain our rights under our licenses relating to these product candidates.

We are required to make substantial cash payments, achieve specified milestones and satisfy other conditions, including filing for and obtaining marketing approvals and introducing products, to maintain our rights under our licenses, including our licenses from UR Labs, Inc. (relating to MNTX), Sloan-Kettering Institute for Cancer Research (relating to GMK) and Columbia University (relating to PRO 542). We may not be able to maintain our rights under these licenses.

Under our license agreements relating to GMK and PRO 542, we are required, among other things, to have filed for marketing approval for a drug by 2000 and to have commenced commercialization of the drug by 2002 (for GMK) and to have filed for marketing approval by 2001 (for PRO 542). We have not achieved these and other milestones and are unlikely to achieve them soon. We are in a similar position with respect to our license agreement with Aquila Biopharmaceuticals, Inc. concerning QS-21, a component of GMK. If we can establish that our failure to achieve these milestones resulted from technical issues beyond our control or delays in clinical studies that could not have been reasonably avoided, we may be entitled to a revision of these milestone dates. Although we believe that we satisfy one or more of these conditions, we may become involved in disputes with our licensors as to our continued right to a license. In addition, at June 1, 2004 we became obligated under our license agreement with Columbia to pay Columbia $225,000. We have accrued this amount but, pending the outcome of discussions with Columbia regarding this payment and other matters relating to the license, we have not yet paid it.

If we do not comply with our obligations under our license agreements, the licensors may terminate them. Termination of any of our licenses could result in our losing our rights to, and therefore being unable to commercialize, any related product. We have had discussions with Sloan-Kettering and Columbia to reach agreement on the revision of applicable milestone dates. We may not, however, reach agreement with these licensors in a manner favorable to us.

We have limited manufacturing capabilities, which could adversely impact our ability to commercialize products.

We have limited manufacturing capabilities, which may result in increased costs of production or delay product development or commercialization. In order to commercialize our product candidates successfully, we or our collaborators must be able to manufacture products in commercial quantities, in compliance with regulatory requirements, at acceptable costs and in a timely manner. The manufacture of our product candidates can be complex, difficult to accomplish even in small quantities, difficult to scale-up for large-scale production and subject to delays, inefficiencies and low yields of quality products. The cost of manufacturing some of our products may make them prohibitively expensive. If adequate supplies of any of our product candidates or related materials are not available to us on a timely basis or at all, our clinical trials could be seriously delayed, since these materials are time-consuming to manufacture and cannot be readily obtained from third-party sources.

We operate pilot-scale manufacturing facilities for the production of vaccines and recombinant proteins. We believe that, for these types of product candidates, these facilities will be sufficient to meet our initial needs for clinical trials. However, these facilities may be insufficient for late-stage clinical trials for these types of product candidates, and would be insufficient for commercial-scale manufacturing requirements. We may be required to expand further our manufacturing staff and facilities, obtain new facilities or contract with corporate collaborators or other third parties to assist with production.

In the event that we decide to establish a commercial-scale manufacturing facility, we will require substantial additional funds and will be required to hire and train significant numbers of employees and comply with applicable regulations, which are extensive. We may not be able to build a manufacturing facility that both meets regulatory requirements and is sufficient for our clinical trials or commercial-scale manufacturing.

We have entered into arrangements with third parties for the manufacture of some of our products. Our third-party sourcing strategy may not result in a cost-effective means for manufacturing products. In employing third-party manufacturers, we will not control many aspects of the manufacturing process, including compliance by these third parties with the FDA's current Good Manufacturing Practices and other regulatory requirements. We may not be able to obtain adequate supplies from third-party manufacturers in a timely fashion for development or commercialization purposes, and commercial quantities of products may not be available from contract manufacturers at acceptable costs.

PRO 542 is a recombinant protein, which generally involves more complex production methods than small-molecule drugs. Manufacturing PRO 542 is highly challenging, and these challenges could increase the cost of production, delay product development or commercialization or otherwise adversely impact our ability to commercialize PRO 542, should we choose to continue this program.

We are dependent on our patents and other intellectual property rights. The validity, enforceability and commercial value of these rights are highly uncertain.

Our success is dependent in part on obtaining, maintaining and enforcing patent and other intellectual property rights. The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves many complex legal and technical issues. There is no clear policy involving the breadth of claims allowed, or the degree of protection afforded, under patents in this area. Accordingly, the patent applications owned by or licensed to us may not result in patents being issued. We are aware of other groups that have patent applications or patents containing claims similar to or overlapping those in our patents and patent applications. We do not expect to know for several years the relative strength or scope of our patent position as compared to these other groups. Furthermore, patents that we own or license may not enable us to preclude competitors from commercializing drugs, and consequently may not provide us with any meaningful competitive advantage.

We own or have licenses to several issued patents. However, the issuance of a patent is not conclusive as to its validity or enforceability. The validity or enforceability of a patent after its issuance by the patent office can be challenged in litigation. Our patents may be successfully challenged. Moreover, we may incur substantial costs in litigation to uphold the validity of patents or to prevent infringement. If the outcome of litigation is adverse to us, third parties may be able to use our patented invention without payment to us. Moreover, third parties may avoid our patents through design innovation.

Also, we can lose the right to patents and other intellectual property licensed to us if the related license agreement is terminated due to a breach by us or otherwise. Some of the patent rights of the PSMA LLC are derived from a license from Cytogen, and some of those rights are derived in turn through license rights Cytogen has acquired. The LLC's patent rights are dependent on each of these licenses.

Generally, we have the right to defend and enforce patents licensed by us, either in the first instance or if the licensor chooses not to do so. In addition, our license agreement with UR Labs regarding MNTX gives us the right to prosecute and maintain the licensed patents. We bear the cost of engaging in some or all of these activities with respect to our license agreements with Sloan-Kettering for GMK, Columbia for PRO 542 and UR Labs for MNTX. With most of our other license agreements, the licensor bears the cost of engaging in all of these activities, although we may share in those costs under specified circumstances. Historically, our costs of defending patent rights, both our own and those we license, have not been material.

We also rely on unpatented technology, trade secrets and confidential information. Third parties may independently develop substantially equivalent information and techniques or otherwise gain access to our technology or disclose our technology, and we may be unable to effectively protect our rights in unpatented technology, trade secrets and confidential information. We require each of our employees, consultants and advisors to execute a confidentiality agreement at the commencement of an employment or consulting relationship with us. However, these agreements may not provide effective protection in the event of unauthorized use or disclosure of confidential information.

If we infringe third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.

There may be patent or other intellectual property rights belonging to others that require us to alter our products, pay licensing fees or cease certain activities. If our products infringe patent or other intellectual property rights of others, the owners of those rights could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any action brought against us, and any license required under any rights that we infringe may not be available on acceptable terms or at all. We are aware of intellectual property rights held by third parties that relate to products or technologies we are developing. For example, we are aware of other groups investigating methylnaltrexone and other peripheral opioid antagonists, PSMA or related compounds and CCR5 monoclonal antibodies and of patents held, and patent applications filed, by these groups in those areas. While the validity of these issued patents, patentability of these pending patent applications and applicability of any of them to our programs are uncertain, if asserted against us, any related patent or other intellectual property rights could adversely affect our ability to commercialize our products.

The research, development and commercialization of a biopharmaceutical often involve alternative development and optimization routes, which are presented at various stages in the development process. The preferred routes cannot be predicted at the outset of a research and development program because they will depend on subsequent discoveries and test results. There are numerous third-party patents in our field, and we may need to obtain a license to a patent in order to pursue the preferred development route of one or more of our products. The need to obtain a license would decrease the ultimate profitability of the applicable product. If we cannot negotiate a license, we might have to pursue a less desirable development route or terminate the program altogether.

We are dependent on third parties for a variety of functions. These arrangements may not provide us with the benefits we expect.

We rely in part on third parties to perform a variety of functions. We are party to numerous agreements which place substantial responsibility on clinical research organizations, consultants and other service providers for the development of our products. We also rely on medical and academic institutions to perform aspects of our clinical trials of product candidates. In addition, an element of our research and development strategy is to in-license technology and product candidates from academic and government institutions in order to minimize investments in early research. We may not be able to maintain any of these relationships or establish new ones on beneficial terms. Furthermore, we may not be able to enter new arrangements without undue delays or expenditures, and these arrangements may not allow us to compete successfully.

We lack sales and marketing experience, which will make us dependent on third parties for their expertise in this area.

We have no experience in sales, marketing or distribution. If we receive marketing approval, we expect to market and sell our products, including MNTX, principally through distribution, co-marketing, co-promotion or licensing arrangements with third parties. We may also consider contracting with a third party professional pharmaceutical detailing and sales organization to perform the marketing function for our products. We currently do not have a marketing partner for MNTX. To the extent that we enter into distribution, co-marketing, co-promotion, detailing or licensing arrangements for the marketing and sale of our products, any revenues we receive will depend primarily on the efforts of third parties. We will not control the amount and timing of marketing resources these third parties devote to our products. In addition, if we market products directly, significant additional expenditures and management resources would be required to develop an internal sales force. We may not be able to establish a successful sales force should we choose to do so.

If we lose key management and scientific personnel on whom we depend, our business could suffer.

We are dependent upon our key management and scientific personnel. In particular, the loss of Dr. Paul J. Maddon, our Chief Executive Officer and Chief Science Officer, could cause our management and operations to suffer. We have an employment agreement with Dr. Maddon, the initial term of which runs through June 30, 2005, subject to an automatic renewal for an additional period of two years unless either party provides ninety days prior notice of non-renewal. See “Item 11. Executive Compensation – Employment Agreements” in our Annual Report on Form 10-K for the year ended December 31, 2004. Neither we nor Dr. Maddon gave notice of non-renewal. We are currently in discussions with Dr. Maddon regarding the renewal of his employment agreement and expect that the agreement will be renewed. Employment agreements do not, however, assure the continued employment of an employee. We maintain key-man life insurance on Dr. Maddon in the amount of $2.5 million.

In October 2004, our board of directors elected Paul F. Jacobson and Kurt W. Briner as Co-chairmen of the Board in substitution of Dr. Paul J. Maddon, our Chief Executive Officer, Chief Science Officer and a director. Dr. Maddon’s employment agreement with us contains provisions relating to the Chairmanship position. In connection with the renewal of Dr. Maddon’s employment agreement, we intend to clarify that the change in the Chairman position is not inconsistent with Dr. Maddon’s employment agreement with us.

Ronald J. Prentki, our President and a director, notified us on March 4, 2005 of his resignation as an officer and director. Mr. Prentki had been responsible for our business development, corporate communications, finance, investor relations, legal and manufacturing and preclinical development functions. We have no present intention to fill the executive position vacated by Mr. Prentki. This resignation will result in additional demands on Dr. Maddon and our other senior executives.

Competition for qualified employees among companies in the biopharmaceutical industry is intense. Our future success depends upon our ability to attract, retain and motivate highly skilled employees. In order to commercialize our products successfully, we may be required to expand substantially our personnel, particularly in the areas of manufacturing, clinical trials management, regulatory affairs, business development and marketing. We may not be successful in hiring or retaining qualified personnel.

If we are unable to obtain sufficient quantities of the raw and bulk materials needed to make our products, our product development and commercialization could be slowed or stopped.

We currently obtain supplies of critical raw materials used in production of MNTX, GMK and other of our product candidates from single sources. In particular, we rely on single-source third-party manufacturers for the supply of both bulk and finished form MNTX. We have a supply agreement with Mallinckrodt Inc., our current supplier of bulk-form MNTX, which has an initial term that expires on January 1, 2008. We do not have long-term contracts with any of our other suppliers. In addition, commercialization of GMK requires an adjuvant, QS-21, available only from Antigenics Inc. Our existing arrangements may not result in the supply of sufficient quantities of our product candidates needed to accomplish our clinical development programs, and we may not have the right or capability to manufacture sufficient quantities of these products to meet our needs if our suppliers are unable or unwilling to do so. Any delay or disruption in the availability of raw materials would slow or stop product development and commercialization of the relevant product.

A substantial portion of our funding comes from federal government grants and research contracts. We cannot rely on these grants or contracts as a continuing source of funds.

A substantial portion of our revenues to date has been derived from federal government grants and research contracts. Although no new grants or contracts were awarded in the first quarter of 2005, in 2004 we were awarded, in the aggregate, approximately $9.2 million in NIH grants and research contracts in addition to previous years' awards. We cannot rely on grants or additional contracts as a continuing source of funds. Moreover, funds available under these grants and contracts must be applied by us toward the research and development programs specified by the government rather than for all our programs generally. For example, the $28.6 million contract awarded to us by the NIH in September 2003 must be used by us in furtherance of our efforts to develop an HIV vaccine. The government's obligation to make payments under these grants and contracts is subject to appropriation by the U.S. Congress for funding in each year. Moreover, it is possible that Congress or the government agencies that administer these government research programs will decide to scale back these programs or terminate them due to their own budgetary constraints. Additionally, these grants and research contracts are subject to adjustment based upon the results of periodic audits performed on behalf of the granting authority. Consequently, the government may not award grants or research contracts to us in the future, and any amounts that we derive from existing grants or contracts may be less than those received to date.

If health care reform measures are enacted, our operating results and our ability to commercialize products could be adversely affected.

In recent years, there have been numerous proposals to change the health care system in the U.S. and in foreign jurisdictions. Some of these proposals have included measures that would limit or eliminate payments for medical procedures and treatments or subject the pricing of pharmaceuticals to government control. In some foreign countries, particularly countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In addition, as a result of the trend towards managed health care in the U.S., as well as legislative proposals to reduce government insurance programs, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drug products. Consequently, significant uncertainty exists as to the reimbursement status of newly approved health care products.

If we or any of our collaborators succeed in bringing one or more of our products to market, third-party payors may establish and maintain price levels insufficient for us to realize an appropriate return on our investment in product development. Significant changes in the health care system in the U.S. or elsewhere, including changes resulting from adverse trends in third-party reimbursement programs, could have a material adverse effect on our operating results and our ability to raise capital and commercialize products.

We are exposed to product liability claims, and in the future we may not be able to obtain insurance against these claims at a reasonable cost or at all.

Our business exposes us to product liability risks, which are inherent in the testing, manufacturing, marketing and sale of pharmaceutical products. We may not be able to avoid product liability exposure. If a product liability claim is successfully brought against us, our financial position may be adversely affected.

Product liability insurance for the biopharmaceutical industry is generally expensive, when available at all. We have obtained product liability insurance in the amount of $5.0 million per occurrence, subject to a deductible and a $5.0 million aggregate limitation. In addition, where local statutory requirements exceed the limits of our existing insurance or where local policies of insurance are required, we maintain additional clinical trial liability insurance to meet these requirements. Our present insurance coverage may not be adequate to cover claims brought against us. In addition, some of our license and other agreements require us to obtain product liability insurance. Adequate insurance coverage may not be available to us at a reasonable cost in the future.

We handle hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business. If we are involved in a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure.

Our research and development work and manufacturing processes involve the use of hazardous, controlled and radioactive materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials. Despite procedures that we implement for handling and disposing of these materials, we cannot eliminate the risk of accidental contamination or injury. In the event of a hazardous waste spill or other accident, we could be liable for damages, penalties or other forms of censure. In addition, we may be required to incur significant costs to comply with environmental laws and regulations in the future.

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Our stock price has a history of volatility. You should consider an investment in our stock as risky and invest only if you can withstand a significant loss.

Our stock price has a history of significant volatility. Between January 1, 2002 and March 31, 2005, our stock price has ranged from $3.82 to $24.40 per share. At times, our stock price has been volatile even in the absence of significant news or developments relating to us. Moreover, the stocks of biotechnology companies and the stock market generally have been subject to dramatic price swings in recent years. Factors that may have a significant impact on the market price of our common stock include:

- the results of clinical trials and preclinical studies involving our products or those of our competitors;
- changes in the status of any of our drug development programs, including delays in clinical trials or program terminations;
- developments regarding our efforts to achieve marketing approval for our products;
- announcements of technological innovations or new commercial products by us, our collaborators or our competitors;
- developments in our relationships with collaborative partners;
- developments in patent or other proprietary rights;
- governmental regulation;
- changes in reimbursement policies or health care legislation;
- public concern as to the safety and efficacy of products developed by us, our collaborators or our competitors;
- our ability to fund on-going operations;
- fluctuations in our operating results; and
- general market conditions.

Our principal stockholders are able to exert significant influence over matters submitted to stockholders for approval.

Dr. Maddon and stockholders affiliated with Tudor Investment Corporation together beneficially own or control approximately 28% of our outstanding shares of common stock. These persons, should they choose to act together, could exert significant influence in determining the outcome of corporate actions requiring stockholder approval and otherwise control our business. This control could have the effect of delaying or preventing a change in control of us and, consequently, could adversely affect the market price of our common stock.

Anti-takeover provisions may make the removal of our Board of Directors or management more difficult and discourage hostile bids for control of our company that may be beneficial to our stockholders.

Our Board of Directors is authorized, without further stockholder action, to issue from time to time shares of preferred stock in one or more designated series or classes. The issuance of preferred stock, as well as provisions in certain of our stock options that provide for acceleration of exercisability upon a change of control, and Section 203 and other provisions of the Delaware General Corporation Law could:

- make the takeover of Progenics or the removal of our Board of Directors or management more difficult;
- discourage hostile bids for control of Progenics in which stockholders may receive a premium for their shares of common stock; and
- otherwise dilute the rights of holders of our common stock and depress the market price of our common stock.

If there are substantial sales of our common stock, the market price of our common stock could decline.

Sales of substantial numbers of shares of common stock could cause a decline in the market price of our stock. We require substantial external funding to finance our research and development programs and may seek such funding through the issuance and sale of our common stock. In addition, some of our stockholders are entitled to require us to register their shares of common stock for offer or sale to the public.

Also, we have filed Form S-8 registration statements registering shares issuable pursuant to our equity compensation plans. Any sales by existing stockholders or holders of options may have an adverse effect on our ability to raise capital and may adversely affect the market price of our common stock.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our primary investment objective is to preserve principal while maximizing yield without significantly increasing our risk. Our investments consist of taxable auction securities, euro dollar bonds, and corporate notes. Our investments totaled $20.9 million at March 31, 2005. Approximately $13.4 million of these investments had fixed interest rates, and $7.5 million had interest rates that were variable.

Due to the conservative nature of our short-term fixed interest rate investments, we do not believe that we have a material exposure to interest rate risk. Our fixed-interest-rate long-term investments are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair values of these investments due to differences between the market interest rate and the rate at the date of purchase of the investment. A 100 basis point increase in the March 31, 2005 market interest rates would result in a decrease of approximately $0.05 million in the market values of these investments.

Item 4. Controls and Procedures

The Company maintains “disclosure controls and procedures,” as such term is defined under Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934, that are designed to ensure that information required to be disclosed in the Company’s Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to the Company’s management, including its Chief Executive Officer and Principal Financial and Accounting Officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, the Company’s management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and the Company’s management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. We also established a Disclosure Committee that consists of certain members of the Company’s senior management.

The Disclosure Committee, under the supervision and with the participation of the Company’s senior management, including the Company’s Chief Executive Officer and Principal Financial and Accounting Officer, carried out an evaluation of the effectiveness of the design and operation of the Company’s disclosure controls and procedures as of the end of the period covered by this report. Based upon their evaluation and subject to the foregoing, the Chief Executive Officer and Principal Financial and Accounting Officer concluded that the Company’s disclosure controls and procedures were effective.

There have been no changes in the Company’s internal control over financial reporting that occurred during the Company’s last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II – OTHER INFORMATION

Item 6. Exhibits

(a) Exhibits

10.1	Supply Agreement, dated January 1, 2005, between the Registrant and Mallinckrodt Inc. (confidential treatment has been requested as to certain portions, which portions have been omitted and filed separately with the Commission)
18.1	Independent Registered Public Accounting Firm’s Preferability Letter Regarding a Change in Accounting Principle
31.1	Certification of Paul J. Maddon, M.D., Ph.D., Chairman and Chief Executive Officer of the Registrant, pursuant to Rule 13a-14 (a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2	Certification of Robert A. McKinney, Chief Financial Officer and Vice President, Finance and Operations (Principal Financial and Accounting Officer) of the Registrant, pursuant to Rule 13a-14(a) and Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended
32	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROGENICS PHARMACEUTICALS, INC.

Date: May 10, 2005

By: **/s/ Robert A. McKinney**
Robert A. McKinney
Chief Financial Officer
(Duly authorized officer of the Registrant and
Principal Financial and Accounting Officer)

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EXHIBIT 10.1

PROGENICS SUPPLY AGREEMENT

This supply agreement (the "Supply Agreement") is made and entered into effective on and as of the 1st day of January, 2005 (the "Effective Date"), by and between the Pharmaceutical Group of Mallinckrodt Inc. ("Mallinckrodt") and Progenics Pharmaceuticals, Inc. ("Progenics").

WHEREAS, Progenics has need of a certain pharmaceutical compound known as Methylnaltrexone (hereinafter "MNTX" or "Product") and is desirous of having MNTX manufactured by Mallinckrodt and of purchasing a portion of its needs for MNTX from Mallinckrodt, on the terms and conditions set forth herein; and

WHEREAS, Mallinckrodt is capable and desirous of undertaking the supply of MNTX for Progenics in accordance with the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises, covenants and representations of the parties set forth herein, and other good and sufficient consideration receipt of which is hereby acknowledged, Progenics and Mallinckrodt agree as follows:

1. Supply of MNTX .

(a) For the consideration provided herein and in accordance with all terms, conditions, representations and warranties set forth herein, and for the Term (as defined in Section 15(a) below), Mallinckrodt will provide Progenics with such amounts of MNTX as Progenics shall order. Progenics, for its part, agrees that it will purchase [*] of its Requirements for MNTX from Mallinckrodt hereunder during every Contract Year hereof [*]. For purposes of the immediately preceding sentence, (i) "Contract Year" shall mean and refer to each consecutive [*] period during the Term coinciding with the calendar year and (ii) "Requirements" shall mean all of Progenics' requirements for the commercial sale or non-commercial use of MNTX by Progenics during any given Contract Year including that portion of its requirements that Progenics flight be capable of producing for itself or sourcing from any of its affiliates.

(b) The price to Progenics for MNTX Delivered (as defined below in this subsection (b)) pursuant to the terms of this Agreement shall be determined in accordance with the provisions of Section 4 hereof. The term "Delivered" shall mean, with respect to any MNTX ordered by Progenics, "delivery" of MNTX by Mallinckrodt and "acceptance" of such MNTX by Progenics, as such terms are defined in paragraphs (i) and (ii) below. For purposes of this Supply Agreement,

(i) delivery of a shipment of MNTX shall occur upon Progenics' receipt of (A) such shipment of MNTX and (B) a certificate of analysis from Mallinckrodt relating to such shipment; and

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(ii) acceptance shall be deemed to occur upon the earlier of (A) written notice of acceptance by Progenics after delivery or (B) [*] after delivery; provided Progenics is not required to accept any Defective Product (as defined in Section 6(a) herein) or any Product shipped to Progenics with respect to which testing samples of Product in designated containers have not been shipped simultaneously, in accordance with Progenics' shipment instructions (including, but not limited to, amount, packaging and shipment of Product), to a testing laboratory designated by Progenics to test the Product.

(c) The specifications and testing methods for MNTX, including without limitation the packaging specifications (such specifications and testing methods being referred to herein as the "Specifications") are set forth on Exhibit A attached hereto, which Specifications will also be attached to the quality agreement between Progenics and Mallinckrodt, the final form of which shall be negotiated by the parties in good faith and executed concurrently with the execution of this Supply Agreement (the "Quality Agreement"), and shall be attached hereto as Exhibit B. In the event of any conflict or inconsistency between the terms of this Supply Agreement and the Quality Agreement, the former shall prevail in every case.

(d) The Specifications may be modified from time to time by the mutual agreement of Mallinckrodt and Progenics; provided that, if Progenics requests that any amendment be made to the Specifications in order to conform to current guidelines and the requirements of the Food and Drug Administration ("FDA") and substantially comparable regulations of the European Union ("EU"), Canada and Japan, Mallinckrodt will not withhold or delay its agreement to any such amendment to the Specifications; provided further that, if Progenics requests that any amendment be made to the Specifications in order to conform to current guidelines and the requirements of any other governmental regulatory agency, which has jurisdiction to regulate products such as MNTX in any country where MNTX is submitted for approval for commercial sale, Mallinckrodt will use its [*] to comply with any such amendment to the Specifications. Mallinckrodt warrants and represents that all MNTX supplied to Progenics hereunder shall be manufactured and stored in accordance with the Specifications in effect at the time of such manufacture and in accordance with the terms of the Quality Agreement.

(e) Mallinckrodt warrants and represents that all MNTX supplied hereunder shall be manufactured by Mallinckrodt in full compliance with current Good Manufacturing Practices ("cGMP") as determined by the FDA and substantially comparable regulations of the EU, Canada, Japan or any other foreign regulatory authority (collectively referred hereinafter as "Regulatory Agencies") using the manufacturing process described in Mallinckrodt's Drug Master Files ("Product DMF").

(f) Mallinckrodt warrants and represents that the Product DMF currently on file for MNTX complies with all Regulatory Agencies' rules and regulations and that any Product DMF for MNTX filed in the future will be filed and maintained in accordance with all Regulatory Agency's rules and regulations. Mallinckrodt shall notify Progenics in writing as soon as it becomes aware and as far in advance as is reasonably possible under the circumstances, of any proposed changes related to the Product DMF, such notification to be in conformance with Regulatory Agencies' guidelines, and the Drug Master File regulations contained in 21 CFR 314,420(c). In addition, Mallinckrodt shall obtain prior approval from Progenics before making any "major (prior approval supplement) changes" to Mallinckrodt's DMF for MNTX as specified in the FDA's Guidance for Industry Changes to an Approved NDA or ANDA dated April 2004, unless any such changes would prevent Mallinckrodt from remaining in compliance with the rules, regulations and directions of U.S. governmental regulatory agencies that have jurisdiction over Mallinckrodt's DMF.

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(g) The parties acknowledge that Mallinckrodt has validated its primary manufacturing facility at the St. Louis, Missouri plant. With respect to previous purchase orders accepted by Mallinckrodt prior to execution of this Supply Agreement, Mallinckrodt has validated the manufacturing process for MNTX manufacture, in batches of [*] , at a secondary manufacturing center located at Mallinckrodt's St. Louis, Missouri plant. Such validation shall be completed prior to execution of this Supply Agreement. Mallinckrodt agrees that it shall produce and supply orders for MNTX only at the St. Louis facility in manufacturing centers validated for MNTX in [*] batch sizes or other batch sizes as agreed by Progenics, that are fully cGMP compliant and which have no FDA approved pharmaceutical ingredient ("API") violations. In addition, Mallinckrodt may not subcontract the manufacture of MNTX to any subcontractor.

(h) Both Mallinckrodt and Progenics agree to monitor new requirements concerning, and work with the FDA on steps to reduce the potential levels of, [*] with respect to all Product produced pursuant to the terms of this Agreement after [*], unless an earlier time is specified by the FDA or other regulatory agency of the EU, Canada or Japan. In addition, Mallinckrodt agrees to monitor the next [*] production lots of MNTX and work on [*].

(i) Notwithstanding Progenics' purchase obligations set forth in Section 1(a) above, in the event (i) Mallinckrodt fails to deliver the amount of MNTX specified in a binding purchase order within [*] of the delivery date specified in such binding purchase order on [*] occasions in any Contract Year, (ii) Progenics determines that any MNTX is not in compliance with the Specifications or the equivalent requirements of any Regulatory Agency, (iii) Progenics determines that any MNTX is Defective Product in accordance with Section 6 or (iv) Progenics determines that it is unable to use Product because of Mallinckrodt's violation of Section 1(f) hereunder, then Progenics shall have the right to purchase from another source without penalty an aggregate amount of MNTX equal to the shortfall in supply or to the amount of defective or non-compliant Product as specified in (i), (ii), (iii) and (iv) above, as applicable. Any third party source supplying Product hereunder shall be given a reasonable amount of lead time to prepare and deliver the Product. The quantity of MNTX purchased by Progenics from other sources shall not be included when calculating Progenics' Requirements of MNTX for purposes of determining whether Progenics has met its Minimum Purchase Obligation pursuant to Section 1(a) herein.

2. Raw Materials .

Subject to the provisions of Section 4 below, all raw materials and other resources required in connection with the production of MNTX to be supplied hereunder shall be provided by Mallinckrodt at its cost and expense. Mallinckrodt warrants and represents that it has access to all necessary raw materials in order to produce MNTX in accordance with the Specifications. To the extent permitted by applicable laws and regulations, Mallinckrodt shall, at all times during the Term, maintain on hand an approximate [*] supply of MNTX raw materials or a combination of MNTX raw materials and finished MNTX sufficient to cover the first [*] of each Rolling Forecast (as defined below). Such raw materials and/or finished MNTX shall meet the requirements set forth in this Supply Agreement.

* CONFIDENTIAL TREATMENT REQUESTED

3. Quality Control .

(a) Mallinckrodt will ensure that it has the facilities, equipment, instrumentation, resources and trained personnel to provide all raw materials, in-process and product assays, analysis and other testing as compliance with Regulatory Agencies' standards may require in connection with Mallinckrodt's supply of MNTX hereunder. Mallinckrodt shall provide a complete certificate of analysis and any other document required by the Quality Agreement for each lot of finished MNTX supplied hereunder at the time of shipment.

(b) Mallinckrodt shall maintain complete and accurate documentation of all validation data, stability testing data, batch records, quality control and laboratory testing and any other data required under Regulatory Agencies' requirements in connection with the supply of MNTX hereunder. Further, Mallinckrodt shall make all such documentation available to Progenics, upon reasonable request, to the extent required to complete an audit pursuant to Section 9(a) below.

(c) Mallinckrodt shall perform stability studies and supply to Progenics a stability summary report. In addition, upon written request by Progenics, Mallinckrodt shall supply to Progenics stability data requested by the FDA for compliance with the requirements of any New Drug Application or any Investigational New Drug Application. In addition, Mallinckrodt shall notify Progenics if a stability test failure occurs. In addition, Progenics may review all stability data during any audits carried out pursuant to Section 9(a) below.

(d) Mallinckrodt agrees that it will not engage in any act which causes any packaged and labeled MNTX produced by Mallinckrodt to become adulterated or misbranded within the meaning of the federal Food, Drug and Cosmetic Act, as amended or equivalent regulation of any Regulatory Agency.

4. Compensation for Services Performed by Mallinckrodt .

(a) Progenics shall pay Mallinckrodt, for MNTX Delivered in any particular Contract Year during the Term, in accordance with the prices set forth on the attached Schedule 1. Such prices are referred to herein as "Product Prices" or, individually, as a "Product Price".

(b) [*]

(c) [*]

(d) [*]

(e) [*]

(f) [*]

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5. Forecasts, Order Placement and Delivery .

(a) Progenics will submit to Mallinckrodt, in writing before the commencement of each calendar quarter commencing after the date of execution of this Agreement and during the Term, a forecast of the anticipated amount of its orders for MNTX hereunder during each of the [*] beginning with the first day of each calendar quarter that follows the calendar quarter in which a forecast is submitted (the "Rolling Forecast"). Mallinckrodt shall provide Progenics with written notice as soon as reasonably practicable if it cannot meet Progenics' stated demand in any Rolling Forecast. Progenics may submit one or more purchase orders for MNTX, in the form attached as Exhibit C hereto, during the [*] (the "Binding Period") in an amount not to exceed [*] of the amount forecasted in such Rolling Forecast for each such [*]. Such purchase orders (provided they are consistent with the terms hereof) shall be firm and binding on Progenics and Mallinckrodt. All purchase orders submitted by Progenics pursuant to this Section 5(a) shall be hereinafter referred to as "Binding Purchase Order(s)". Mallinckrodt shall acknowledge in writing its receipt of each Binding Purchase Order within [*] of receipt of any such Binding Purchase Order.

(b) The amount forecasted for the [*] (the "Non-Binding Period") shall be considered non-binding and shall be used by Mallinckrodt only for production planning purposes; provided that, Progenics may issue additional purchase orders during the Binding Period for any amount forecasted in the Non-Binding Period ("Additional Purchase Order(s)"). If Mallinckrodt accepts any such Additional Purchase Order, it shall acknowledge its acceptance in writing within [*] of receipt of any such Additional Purchase Order. Except as provided in Section 6 hereunder, an executed Additional Purchase Order shall be binding on Mallinckrodt and Progenics.

(c) MNTX shall be ordered by Progenics only in writing and in the form attached hereto as Exhibit C. Mallinckrodt will not accept verbal orders of any kind for the production of MNTX. Any purchase order will contain the following information: (i) the precise quantity of MNTX desired, (ii) the dates by which the ordered MNTX must be ready for release by Progenics' quality assurance function for shipment, (iii) the anticipated shipping destination for any MNTX and (iv) such other information as mutually agreed to by the parties.

(d) Notwithstanding any other provision hereof, the terms of any purchase order, confirmation or any other document submitted by either party in connection herewith shall have no force or effect to the extent they are in conflict or inconsistent with the terms of this Supply Agreement.

(e) Mallinckrodt shall fulfill and deliver each Binding Purchase Order and each accepted Additional Purchase Order by the date specified in any such purchase order. MNTX shall be delivered [*]. Title to MNTX and risk of loss shall [*].

6. Acceptance and Resection and Recalls .

(a) Upon delivery, Progenics shall have the right, but not the obligation, to inspect and test MNTX. If Progenics reasonably determines that any MNTX is defective in material or workmanship, not in conformance with the Specifications or the equivalent requirement of any Regulatory Agency (if and as applicable), is adulterated or misbranded, or is otherwise not in conformity with both this Supply Agreement and the Quality Agreement (any such MNTX is hereinafter referred to as "Defective Product"), then Progenics, in addition to any other rights it may have under this Supply Agreement, may reject and return such Defective Product to Mallinckrodt. At the time of any such rejection, Progenics shall provide Mallinckrodt with a written notice describing in reasonable detail the reasons for the rejection. Progenics will, at Mallinckrodt's option, either return the Defective Product to Mallinckrodt or destroy or dispose of such Defective Product in the least expensive manner which complies with all relevant local, state and federal environmental laws pertaining to the disposal of such materials. In any event, Mallinckrodt shall be responsible for [*].

(b) In the event of rejected Defective Product under this Supply Agreement Mallinckrodt will, at Progenics' sole option and as Progenics' sole remedy, either (i) replace, within [*], the rejected Defective Product that has either been returned or destroyed with MNTX that is not Defective Product on an expedited basis or (ii) provide [*] of any amount paid hereunder by Progenics for such Defective Product. Any replacement MNTX delivered to Progenics shall be invoiced at [*].

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(c) Any MNTX received by Progenics from Mallinckrodt that has not been rejected by Progenics within [*] after receipt shall be deemed to have been accepted.

(d) If at any time Progenics reasonably decides to or is required to initiate a MNTX recall, withdrawal or field correction with respect to, or if there is any governmental seizure of, its products containing any MNTX supplied hereunder which action is due, in whole or in part, to (i) a failure of any of the MNTX manufactured by Mallinckrodt hereunder to conform to the Specifications (including, without limitation, it being adulterated or misbranded), the Quality Agreement, or any warranty or covenant or other requirement set forth in this Supply Agreement, (ii) the failure by Mallinckrodt to comply with any applicable law, rule, regulation, standard, court order or decree or (iii) the negligent or intentional wrongful act or omission of Mallinckrodt in connection with the production of MNTX hereunder, Progenics will notify Mallinckrodt promptly of the details regarding such action, including providing copies of all relevant documentation concerning such action. Mallinckrodt will assist Progenics in investigating any such situation and all regulatory contacts that are made and all activities concerning seizure, recall, withdrawal or field correction will be jointly coordinated by Progenics and Mallinckrodt; provided however, that any and all final determinations as to actions to be taken with respect to any recall, withdrawal, field correction or governmental seizure of dosage products containing MNTX shall be within the sole discretion of Progenics.

(e) [*]

7. Regulatory Compliance .

(a) Mallinckrodt will comply with all federal, state and local laws, regulations and standards applicable to production by Malinckrodt and its performance of its obligations hereunder. Mallinckrodt will notify Progenics promptly of all FDA, Drug Enforcement Agency ("DEA") or other Regulatory Agencies' inspections if such inspection impacts, or is reasonably expected to impact, Mallinckrodt's ability to meet its obligations under this Agreement or the Quality Agreement.

(b) Mallinckrodt will promptly furnish Progenics with pertinent portions of all FDA and DEA or other Regulatory Agencies' inspection reports and related correspondence to the extent such reports and correspondence relate to, in whole or in part, or affect the facilities, procedures, assays, validation methodology, personnel or other aspects of operations utilized by Mallinckrodt in its performance hereunder as and when such reports and correspondence become available to Mallinckrodt.

(c) Mallinckrodt will notify Progenics immediately of any warning (including, but not limited to, any FDA Form 483 and any equivalent issuance by any Regulatory Agencies), citation, indictment, claim, lawsuit or proceeding issued or instituted by any federal, state or local governmental entity or agency against Mallinckrodt or any of its affiliates or of any revocation of any license or permit issued to Mallinckrodt or any of its affiliates, to the extent that any such occurrence has any impact whatsoever on the ability of Mallinckrodt to manufacture MNTX hereunder.

* CONFIDENTIAL TREATMENT REQUESTED

(d) To the extent possible under applicable circumstances, Mallinckrodt will provide advance notice to Progenics of any meeting with FDA or Regulatory Agencies on regulatory issues relating to MNTX or issues affecting the ability of Mallinckrodt to manufacture MNTX in its facilities. Mallinckrodt shall also, to the extent possible under applicable circumstances, provide to Progenics notification and a copy of all submissions to such Regulatory Agencies and/or the FDA no less than [*] prior to the date of submission; provided that, Mallinckrodt may exclude in such copies submitted to Progenics information relating to Mallinckrodt's proprietary information.

(e) Mallinckrodt will permit Progenics to reference the Product DMFs for all regulatory filings, with respect to any Regulatory Agency, for its finished dosage form product containing MNTX. Mallinckrodt will provide an authorization letter to the FDA and/or the Regulatory Agencies permitting such reference as contemplated herein. Mallinckrodt shall complete and provide to Progenics the applicant portion or open sections that are the substantial equivalent of a Product DMF with respect to any filings that Progenics makes with Regulatory Agencies. Mallinckrodt shall provide reasonable technical and regulatory assistance to Progenics relating to such regulatory filings for its finished dosage form product.

(f) In accordance with Progenics' MNTX NDA for the treatment of Opioid Induced Constipation in Advanced Medical Illness ("AMI"), Mallinckrodt shall not supply [*] for the manufacture of MNTX commercial vials. However, within [*] of approval of the MNTX NDA for AMI, Progenics shall file with the FDA a [*].

8. Certain Representations and Warranties of Mallinckrodt .

(a) Mallinckrodt represents and warrants that all MNTX sold hereunder will (i) be produced in full compliance with cGMPs applicable to the MNTX and in accordance with the Quality Agreement to be attached, and (ii) will meet all Specifications.

(b) Mallinckrodt represents and warrants that there is no claim, suit, proceeding or investigation pending or, to the knowledge of Mallinckrodt, threatened against Mallinckrodt or any of its affiliates which might prevent or interfere with Mallinckrodt's performance under this Supply Agreement.

(c) Mallinckrodt represents and warrants to Progenics that MNTX sold hereunder by Mallinckrodt will not be:

(i) in violation of Sections 5 or 12 of the Federal Trade Commission Act or improperly labeled under applicable Federal Trade Commission Trade Practice Rules, as and to the extent applicable hereunder,

(ii) adulterated or misbranded within the meaning of the federal Food, Drug and Cosmetic Act, as amended, and equivalent regulations of any Regulatory Agency or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially identical with those contained in the federal Food, Drug and Cosmetic Act, or articles which may not under the provisions of Sections 404 or 505 of said Act be introduced into interstate commerce or which may not under substantially similar provisions of any state or municipal law be introduced into commerce,

(iii) manufactured or sold in violation of the federal Controlled Substances Act, as amended, or any applicable state law,

(iv) manufactured or sold in violation of any of the provisions of the Fair Labor Standards Act of 1938, as amended,

(v) manufactured in violation of any other applicable federal, state or local law or regulation, or

(vi) manufactured in violation of any agreement (commercial or otherwise), judgment, order or decree to which Mallinckrodt is a party.

* CONFIDENTIAL TREATMENT REQUESTED

(d) Mallinckrodt certifies that neither it nor any of its affiliates nor any member of their staff has been disqualified or debarred by the FDA for any purpose.

(e) Mallinckrodt warrants and represents that neither it nor any of its affiliates nor any member of their staff have been charged with or convicted under federal law for conduct relating to the development or approval, or otherwise relating to the regulation of MNTX or any other drug under the Generic Drug Enforcement Act of 1992 or any other relevant statute, law or regulation.

(f) Mallinckrodt is not aware of, nor are there any known facts or circumstances that reasonably should cause Mallinckrodt to be aware of, any infringement of any patents or other intellectual property rights of third parties that might occur as a consequence of the manufacture and supply of MNTX by Mallinckrodt to Progenics hereunder.

(g) Mallinckrodt agrees that, at all times during the Term hereof, the Product Price of MNTX payable by Progenics to Mallinckrodt shall not exceed [*].

(h) EXCEPT AS SET FORTH ABOVE IN THIS SECTION 8, MALLINCKRODT MAKES NO OTHER WARRANTY OR REPRESENTATION, EXPRESS OR IMPLIED, CONCERNING ITS PERFORMANCE HEREUNDER, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO "MNTX". [*]

9. Facility and Record Access and Audit; Diligence Cooperation .

(a) Progenics, through its employees, consultants or other representatives (including, without limitation, prospective and actual licensees of Progenics), will have the right during normal business hours and upon advance arrangement with Mallinckrodt to audit Mallinckrodt's manufacturing operations to determine whether or not Mallinckrodt is complying in all respects with its obligations hereunder. Progenics warrants that all such audits shall be carried out in a manner calculated not to unreasonably interfere with Mallinckrodt's conduct of business and that all confidential information of Mallinckrodt disclosed to Progenics as a result of such audits shall be afforded the protections set forth in Section 12 hereof. Further, Progenics agrees to comply with all of Mallinckrodt's safety and security requirements during any visits to the Mallinckrodt facilities.

(b) In addition to the access to its facilities provided in Section 9(a) above, Mallinckrodt will also cooperate with and assist Progenics in its discussions with prospective licensees by responding to such prospective licensees' due diligence inquiries relating to MNTX manufacture and related subject matter, at the cost and expense of Progenics.

10. Force Majeure .

Neither party to this Supply Agreement shall be liable for or be in breach of any provision hereof for any failure or delay on its part to perform any obligation (other than the obligation to make payments when due) under any provision of this Supply Agreement because of an event of "force majeure", including, but not limited to, any act of God, fire, flood, explosion, unusually severe weather, war, insurrection, riot, sabotage, labor unrest, strikes or work stoppages or any other cause whatsoever, whether similar or dissimilar to those enumerated herein, beyond any reasonable possibility of control of such party, if and only if the party affected shall have used all reasonable efforts under the circumstances to avoid such occurrence and to remedy it promptly if it shall have occurred. If an event of force majeure causes a failure or delay in performance hereunder by Mallinckrodt for more than [*], Progenics, at its option, may (i) terminate this Supply Agreement effective upon written notice to Mallinckrodt or (ii) may extend the delivery or performance period by the amount of time during which such delivery or performance was omitted or delayed.

11. Relationship of Parties .

For all purposes hereof, Mallinckrodt shall be deemed to be an independent contractor and this Supply Agreement shall not create an agency, partnership, joint venture, or employer/employee relationship between Progenics and Mallinckrodt, and nothing hereunder shall be deemed to authorize either party hereto to act for, represent or bind the other or any of its affiliates except as expressly provided in this Supply Agreement.

* CONFIDENTIAL TREATMENT REQUESTED

12. Confidentiality .

(a) Progenics and Mallinckrodt shall maintain in confidence and not use or disclose to any third party, except as is specifically contemplated herein or is otherwise necessary to perform their respective obligations under this Supply Agreement, and then only on a confidential basis satisfactory to both parties, any confidential information of the other, including without limitation any such information that represents or incorporates business and technical information, experience or data regarding any facility, programs, laboratories, processes, products, costs, equipment operation or customers, relating to the manufacture or sale of MNTX hereunder. The foregoing obligations of confidentiality and non-use shall survive the termination or expiration of this Supply Agreement for a period of [*]. Nothing herein shall prevent either party from disclosing any information (i) required by statute or governmental regulations or by legal process (including any rule or regulation of the Securities and Exchange Commission, the NASDAQ National Market or any other exchange or self-regulatory organization) to be disclosed in a judicial or administrative proceeding after using reasonable efforts to avoid disclosure, minimize the scope of the disclosure or obtain an appropriate protective order, or (ii) required, in the reasonable opinion of the disclosing party's legal counsel to be disclosed or included in any regulatory filing, or (iii) which has been published or has become part of the public domain other than by acts, omissions or fault of such party, or (iv) which was lawfully received by such party from a third party free of any obligation of confidence to such third party, or (v) that a party can demonstrate from its records was already in its possession prior to receipt thereof, directly or indirectly, from the other party. The party asserting the applicability of one of the exclusions from the obligation of confidentiality set forth in the immediately preceding sentence shall have the burden of proving the applicability of any such exclusion in any particular circumstance and shall, in the case of clauses (i) through (v) provide advanced written notice of any contemplated disclosure pursuant thereto to the other party, unless prohibited by law or legal process.

(b) Each party acknowledges that any breach by it of the confidentiality obligations set forth in this Section 12 would cause the other party irreparable harm for which compensation by monetary damages would be inadequate and, therefore, the party that has been harmed by any such breach shall have the right to an injunction or decree for specific performance, in addition to any other rights and remedies such party may have at law or in equity.

13. Intellectual Property .

Each party shall retain all right, title and interest in and to any and all inventions, processes, know-how, trade secrets and other intellectual property rights ("Intellectual Property") relating to MNTX that it currently owns. Each party shall own all right, title and interest in and to all Intellectual Property that it solely creates (or that, as between the parties, is created solely on its behalf) in connection with this Agreement.

14. Indemnification .

(a) [*]

(i) [*]

(ii) [*]

(iii) [*]

(b) [*]

(i) [*]

(ii) [*]

(iii) [*]

* CONFIDENTIAL TREATMENT REQUESTED

15. Term and Termination .

(a) Unless sooner terminated in accordance herewith, the initial term of this Supply Agreement shall be for a period commencing on the Effective Date, and ending on the third (3) anniversary thereof. Thereafter, this Supply Agreement shall be automatically renewed for additional and successive one (1) year terms, unless either party shall provide to the other party written notice of an intent not to renew at least six (6) months prior to the end of the initial term or renewal term, as applicable. The term of this Supply Agreement as referred to in this Section 15(a) (including any extension period) is referred to herein as the "Term."

(b) In addition to any other right of termination specifically provided for hereunder, this Supply Agreement may be terminated by either party for cause upon written notice to the other. For purposes of the preceding sentence, "cause" shall mean (without limitation):

(i) any material breach of this Agreement by a party (including, but not limited to, Mallinckrodt's failure to deliver to Progenics the amount of MNTX specified in a binding purchase order within [*] of the delivery date specified in such binding purchase order [*] or more times in any Contract Year) which shall go uncorrected for a period of [*] after written notice of such breach has been given to the defaulting party;

(ii) any material breach of any representation and warranty set forth in this Agreement;

(iii) the institution by a party of voluntary proceedings in bankruptcy or under any insolvency law or law for the relief of debtors;

(iv) the making by a party of an assignment for the benefit of creditors or any dissolution or liquidation;

(v) the filing of an involuntary petition under any bankruptcy or insolvency law against a party, unless such petition is dismissed or set aside within [*] from the date of its filing; or

(vi) the appointment of a receiver or trustee for the assets or business of a party, unless such appointment is dismissed or set aside within [*] from the date of such appointment.

(c) In the event of any termination of this Supply Agreement, for whatever reason, Mallinckrodt shall, notwithstanding the effective date of any termination, fulfill any orders for MNTX that were issued by Progenics and accepted by Mallinckrodt during the [*] as specified in Section 5(a) and any other purchase orders issued prior to the effective date of such termination, and Progenics shall pay Mallinckrodt for any MNTX ordered and Delivered to Progenics at the applicable Product Price.

(d) The representations and warranties of the parties hereunder, covenants which by their terms have effect after the termination or expiration hereof, and the parties' indemnification and confidentiality obligations shall survive termination or expiration of this Supply Agreement.

(e) In the event that Progenics terminates this Agreement in accordance with the terms of Section 15(a) or 15(b) herein or upon expiration of this Agreement, Progenics shall have the right, upon written notice to Mallinckrodt, to submit one or more purchase orders for MNTX up to a maximum of [*] of the aggregate amount reflected in the [*] of its then current [*]. If Progenics makes this election, Mallinckrodt shall produce and deliver to Progenics the full quantity so ordered within [*] of the effective date of any termination by Mallinckrodt or on such other schedule as the parties shall mutually agree.

(f) Upon termination of this Agreement, Mallinckrodt shall maintain and complete the stability program as agreed by the parties hereunder and maintain the MNTX DMFs in accordance with each Regulatory Agency's guidelines.

* CONFIDENTIAL TREATMENT REQUESTED

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16. Remedies Cumulative .

Except as otherwise specifically set forth herein, the remedies provided in this Supply Agreement shall be cumulative and shall not preclude assertion by any party hereto of any other rights (whether legal or equitable in nature) or the seeking of any other remedies against any other party hereto.

17. Binding Effect and Assignment .

This Supply Agreement shall inure to the benefit of and be binding upon the parties hereto, their successors and assigns. Neither party shall, without the prior written consent of the other party, such consent not to be unreasonably withheld or delayed, assign or transfer any of its rights, benefits, obligations, or other interest under this Agreement to any other party; provided that, without seeking the consent of Mallinckrodt, Progenics may assign this agreement, upon [*] written notice, to any agent, collaborator, licensee, distributor or any other entity which is involved, in any capacity, in the sale, promotion, manufacture or distribution of MNTX; provided further that, either Mallinckrodt or Progenics may assign this Agreement, upon [*] written notice, to any of their affiliates.

18. Notice .

All notices, consents, approvals or other notifications required to be sent by one party to the other party hereunder shall be in writing and shall be deemed served upon the other party if delivered by hand or sent by United States registered or certified mail, postage prepaid, with return receipt requested, or by facsimile, air courier or telex, addressed to such other party at the address set out below, or the last address of such party as shall have been communicated to the other party. If a party changes its address, written notice shall be given promptly to the other party of the new address. Notice shall be deemed given, on the day it is sent (in the case of delivery by method other than hand delivery) or the date of delivery (in the case of delivery by hand) in accordance with the provisions of this paragraph. The addresses for notices are as follows.

If to Mallinckrodt:

Mallinckrodt Inc.
c/o Pharmaceuticals Group
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: [*]
Senior Vice President & President
Pharmaceuticals Group

with a copy to:

Mallinckrodt Inc.
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attn: [*]
Vice President – Legal

If to Progenics:

Progenics Pharmaceuticals
777 Old Saw Mill River Road
Tarrytown, NY 10591
Attn: [*]
President

with a copy to:

Progenics Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, NY 10591
Attn: General Counsel

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* CONFIDENTIAL TREATMENT REQUESTED

19. Governing Law and Jurisdiction .

This Agreement shall be governed by and construed in accordance with the substantive and procedural laws (as opposed to the conflicts of law provisions) of the State of New York.

20. Waiver .

The failure by any party to exercise any of its rights hereunder or to enforce any of the terms or conditions of this Supply Agreement on any occasion shall not constitute or be deemed a waiver of that party's rights thereafter to exercise any rights hereunder or to enforce each and every term and condition of this Supply Agreement.

21. Modifications and Entire Agreement .

This Supply Agreement and the Quality Agreement (and all of the exhibits, schedules and attachments hereto and thereto) constitute the entire agreement among the parties on the subject matter defined herein and supersedes all prior oral and written proposals, contracts, agreements, and understandings among the parties relating to the same subject matter. This Supply Agreement may not be amended or modified except by a writing specifically referring to this Supply Agreement and executed by duly authorized representatives of both parties. The obligations of the parties are governed by the terms and conditions of this Supply Agreement and none of the general terms and conditions of any Progenics purchase order or any Mallinckrodt acknowledgment or any substantially similar documents of either party will in any case be controlling or supersede the provisions hereof.

22. Severability .

A determination that any portion of this Supply Agreement is unenforceable or invalid shall not affect the enforceability or validity of any of the remaining portions hereof or of this Supply Agreement as a whole. In the event that any part of any of the covenants, sections or provisions herein may be determined by a court of law or equity to be overly broad or against applicable precedent or public policy, thereby making such covenants, sections or provisions invalid or unenforceable, the parties shall attempt to reach agreement with respect to a valid and enforceable substitute for the deleted provisions, which shall be as close in its intent and effect as possible to the deleted portions.

23. Headings .

The parties agree that the section and article headings are inserted only for ease of reference, shall not be construed as part of this Supply Agreement, and shall have no effect upon the construction or interpretation of any part hereof.

24. Counterparts .

This Supply Agreement may be executed in several counterparts, and each executed counterpart shall be considered an original of this Supply Agreement.

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IN WITNESS WHEREOF, the parties hereto have caused this Supply Agreement to be executed as of the respective dates written below.

PROGENICS PHARMACEUTICALS, INC.

By: **/s/ Ronald J. Prentki**
Ronald J. Prentki
President
Progenics Pharmaceuticals, Inc.
Date: March 8, 2005

MALLINCKRODT INC.
Pharmaceuticals Group
By: **/s/ Michael J. Collins**
Michael J. Collins
Senior Vice & President, Pharmaceuticals
Group, Tyco Healthcare
Date: March 10, 2005

EXHIBIT 18.1

May 10, 2005

Board of Directors
Progenics Pharmaceuticals, Inc.

Dear Directors:

We are providing this letter to you for inclusion as an exhibit to your Form 10-Q filing pursuant to Item 601 of Regulation S-K.

We have been provided a copy of the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2005. Note 2 therein describes a change in accounting principle from recognizing collaborative research and development revenue pursuant to the method described in EITF Issue No. 91-6 to the substantive milestone method. It should be understood that the preferability of one acceptable method of accounting over another for revenue recognition for that type of revenue has not been addressed in any authoritative accounting literature, and in expressing our concurrence below we have relied on management's determination that this change in accounting principle is preferable. Based on our reading of management's stated reasons and justification for this change in accounting principle in the Form 10-Q, and our discussions with management as to their judgment about the relevant business planning factors relating to the change, we concur with management that such change represents, in the Company's circumstances, the adoption of a preferable accounting principle in conformity with Accounting Principles Board Opinion No. 20.

We have not audited any financial statements of the Company as of any date or for any period subsequent to December 31, 2004. Accordingly, our comments are subject to change upon completion of an audit of the financial statements covering the period of the accounting change.

Very truly yours,

/s/ PricewaterhouseCoopers LLP

Exhibit 31.1

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a) UNDER THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Paul J. Maddon, M.D., Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Progenics Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Paul J. Maddon, M.D., Ph.D.

Date: May 10, 2005

Paul J. Maddon, M.D., Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION
PURSUANT TO RULE 13a-14(a) AND RULE 15d-14(a) UNDER THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Robert A. McKinney, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Progenics Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within the registrant, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Robert A. McKinney

Date: May 10, 2005

Robert A. McKinney
Chief Financial Officer

Exhibit 32

**CERTIFICATION PURSUANT
TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned hereby certifies, in his capacity as an officer of Progenics Pharmaceuticals, Inc. (the "Company"), for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Quarterly Report of the Company on Form 10-Q for the period ended March 31, 2005 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial conditions and results of operations of the Company.

Date: May 10, 2005

/s/ Paul J. Maddon, M.D., Ph.D.

Paul J. Maddon, M.D., Ph.D.
Chief Executive Officer

/s/ Robert A. McKinney

Robert A. McKinney
Chief Financial Officer
(Principal Finance and Accounting Officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Progenics Pharmaceuticals, Inc. and will be retained by Progenics Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.